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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application Number	:	10/647,393	Confirmation No.: 2034
Applicant	:	Hans Henrik JOCHUMSEN et al.	
Filed	:	August 26, 2003	
Title	:	A TESTING DEVICE FOR TESTING OR ANALYSING FLUIDS AND A HOLDER AND A STORAGE CONTAINER FOR SUCH DEVICES	
TC/Art Unit	:	2855	
Examiner:	:	TBA	
Docket No.	:	60589.000013	
Customer No.	:	**21967**	

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P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants respectfully submit a certified copy of Danish Patent Application No. PA 2003 00751, filed May 19, 2003, in connection with the above-identified patent application. Applicants claim foreign priority benefits under 35 U.S.C. § 119 from the Danish Application in the above-identified Application filed in the U.S. Patent and Trademark Office on August 26, 2003.

It is believed that no fees are due in connection with the submission of these documents. However, if any fees are determined to be due, the Commissioner is hereby authorized to charge these fees to the undersigned's Deposit Account No. 50-0206.

Respectfully submitted,

HUNTON & WILLIAMS LLP

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Patent application No.: PA 2003 00751

Date of filing: 19 May 2003

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Title: An apparatus for analysing fluid taken from a body

IPC: -

This is to certify that the attached documents are exact copies of the above mentioned patent application as originally filed.

Patent- og Varemærkestyrelsen
Kongeriget Danmark

Patent- og Varemærkestyrelsen
Økonomi- og Erhvervsministeriet

03 October 2003

Pia Høybye-Olsen

PATENT- OG VAREMÆRKESTYRELSEN

AN APPARATUS FOR ANALYSING FLUID TAKEN FROM A BODY

The present invention relates generally to an apparatus for analysing fluid taken from a body, and more in particularly for analysing body fluids from mammals. The apparatus provides an automated real time analysis of milk. Preferred embodiments of the apparatus comprise storage for storing sticks or other kinds of biosensors, an incubator and transferring means. The incubator comprises an incubator disc on which the sticks are to be loaded. During one rotation of the incubator disc the apparatus performs the steps of loading the sticks on to the incubator disc, thermally conditioning of the sticks, dosing of the body fluid, incubation of the sticks carrying the body fluid and analysing the result. Finally the sticks are automatically removed from the incubator disc into the container.

The invention further relates to a method for performing an analysis of body fluids.

BACKGROUND

In recent years analysis instrument have been used in the dairy industry for optimising the production and for quality assurance at all stages along the production line. Some of the analysis instruments are usually installed in special analysing rooms where the environment usually is not so harsh to the equipment or the biosensors that are needed in the process. Whereas others have been manufactured for installation on sites where the environment can have crucial impact on the result of the analysis. For the latter kind of apparatus it is a problem to keep the whole apparatus, and more specifically the sensitive parts inside, separated from environmental influence. Without loosing processing speed or result in high investment costs in the system to which the analysis apparatus should be installed to.

GENERAL DESCRIPTION

As presented above the present invention relates to an apparatus for analyzing chemical contents in a body fluid sample. A preferred embodiment, which will be disclosed in further details in below sections, embodies, in general, the following step:

- a specific volume of a sample of the body fluid is dosaged on a drystick.
- the drystick with dosaged fluid is incubated for a certain time, and
- the result (intensity of color on the stick) is measured by an optical reader.

The main parts of the apparatus are preferably:

- A cylindrical storage for drysticks coontaining two or more different formats of drysticks, stored at controlled temperature and humidity. Means for loading sticks into the storage and for presenting sticks to a stickmover.
- A stickmover, able of transfering sticks of different format from the storage to an incubator.
- A circular incubator receiving sticks from storage, transferring sticks to dosage and reader.
- A dosage system receiving the sample, thermostatating the sample and dosing the sample on the drystick. Adding additional fluids to the stick.

- Two insulating enclosures insulating storage and incubator towards environment and each other, and minimizing the exchange of humidity woth the environment and each other.
- A thermostation system securing a fixed temperature in storage and incubator.
- A cabinet protecting against moisture, water and dust.

Preferred features and effects which are envisaged obtainable by preferred embodiments of the invention are presented in the following lists:

Storage carrousel and reload hatch

- A system enabling a precise positioning of the cartridge in relation to the storage disc, allowing the locking and releasing of the cartridge and the cartridge keeper and a rotation/translation of same presenting the cartridge for removal/insertion, the actuating system being out of physical contact with the storage/keeper/cartridge during the storages operation.

- A circular or linear storage, able of storing different sizes of dry sticks and by a linear or circular movement presenting the drysticks to a transfer mechanism.

- A geometry in the storage carrousel fixing the cartridge in a precise position.

- An integration of positioning fanes in the topdisc of the storage, minimizing the tolerances between cartridge and fanes.

- A reload hatch for accessing the storage room from the side of the storage carrousel, with a mechanism enabling the locking and releasing of a drystick cartridge and a cartridge keeper mounted to the storage geometry, without being in physical contact with the storage carrousel during its normal operation.

- A cartridge keeper able of receiving a user or automatic loaded cartridge with drysticks, and in cooperation with a mechanism, eg in a reload hatch, and the geometry of the storage, precisely positioning and locking the cartridge.

- A mechanism in the keeper pushing the sticks towards the top or the bottom of the cartridge, presenting the sticks to a stickmover.

- A lock in the keeper, positioning the cartridge in a first position, from where the keeper with cartridge can be loaded into a postion close to locked position.

- A mechanism in the keeper allowing a further positioning of the cartridge in the keeper, enabling a locking geometry on the cartridge to engage with the geometry of

the storage, the same mechanism securing the position of the locking geometry of the cartridge in relation to the geometry of the storage.

- A protrusion in the keeper enabling a locking of the keeper to the reload hatch, from a certain opening position of the reload hatch.

- A geometry in the keeper engaging with a keeper pawl in the storage, locking the keeper to the storage.

- A mechanism moving the keeper to a position where a cartridge can be loaded, when the keeper and cartridge are released from the storage disc, eg a spring actuated revolving movement around the front bottom corner of the keeper.

- A mechanism in the reload hatch and reload hatch frame actuated by the opening of same hatch or by another actuator. When opening the reload hatch the mechanism engages with the keeper pawl, which releases the cartridge keeper. Same mechanism engages with the cartridge releasing its locking geometry from the storage disc. These two actuations releases keeper and cartridge, which will move to a position where the cartridge can be removed.

- The use of a molecular sieve in an analyzer for body fluids, to dry and remove ammonia from the air in the storage where the drysticks are stored.

- The molecular sieve material being contained in a container similar to the drystick cartridges, enabling the insertion and removal of the molecular sieve in the storage, in a similar manner as the drystick cartridges

Incubator disc

- A disc with 'teeth' around the periferi allowing a stickmover pawl to insert drysticks of different lengths at optional radial position on the disc. Additionally allowing the stickmover to remove the drysticks from the disc.

- An element called a slot, mounted to the disc, together with the disc forming a guide for the movement of the stick, and a precise positioning of the stick in the vertical and tangential direction. A lock element, eg a spring, eg as part of the slot geometry, fixing the stick in the radial direction, when not pushed by the stickmover, and securing physical contact between the stick and the disc.
- Contact between the stick and the bottom of the disc, allowing the stick to be removed from the disc by a free fall, after the stickmover has pushed the stick out of the slot.

- Fanes as part of the slot, used together with photosensors to position the incubator disc.

- The removal of used sticks from the incubator, by pushing the used stick by a new stick being inserted at the same place in the incubator.

Drives for storage and incubator

- A pretensioning of the timing belt between a stepmotor and a timingpulley, by a spring, making adjustments of the disrtance between stepmotor and pulley unnecessary.

Stick waste container and chute leading to the waste container

- A sliding hatch/fane placed before or in the chute leading to the container or in the container. The fane interacting with a sensor in the open position and another sensor in the closed position, giving the possibility to detect a drystick obstructing the fanes movement. The fane driven by a mechanism (motor with carankshaft and spring) allowing the fane to stop in a position between open and closed, if obstructed by a drystick.

- The fane minimizing the airflow between waste container and incubator.

- A control strategy for stickwaste detection

Stickmover

- A mechanism able of transferring a drystick from the storage to the incubator in a linear motion, by a pawl pushing the stick. A geometry of the pawl in combination with flexibility of the pawl, springloaded guidance of the pawl and a guiding ramp on the cartridge, securing a precise grip on the drystick and an adaption to tolerances in the positioning of cartrtidge, sticks, storage carrousel, stickmover guideway.

- A guidance of the pawl, lifting it as it retracts after delievering a drystick to the incubator, allowing it to pass above the cartridges in the storage.

- The pawls linear motion driven by a teeth rack or a spindle.

- A hatch opened by the passing pawl system, minimizing the air and heat transfer between storage and incubator.

- Control strategy for storage, incubator and stickmover

- A strategy for the control of the stickmover, the storage carrousel and the incubator, enabling a precise positioning during normal operation, and a safe restart after power failure.

- Storage and incubator:
  - Two photosensors and a fane for each position in the storage. At normal operation a fane at a position ahead of the desired stop position for the storage, is detected by the photosensor, and the precise stop position is obtained by counting the steps on the stepmotor driving the storage carrousel, from the fane to stopposition. During restart from power failure the two photosensors are used together with two fanes, to detect whether the storage is in a position where a stick can be transferred. The photosensors being positioned in such a way that they are activated by two fanes, at a storage position suited for sticktransport.

- Stickmover:
  - Two photosensors and two fanes, giving the position of the stickmover (home, in or above cartridge, in guideway, in incubator).

Control strategy at power up

- A positioning of the stepmotors by counting steps from a home position detected by a photosensor, making additionally position feedback unnecessary.

- Protection of the mechanical systems by a surveyance of the stepmotors current, making it possible to stop the stepmotors if eg a drystick is stuck in a guidance.

Beam

- A suspension element positioning the mechanical systems precisely in relation to each other. Enabling a retraction from the cabinet and a fixation at a position where the mechanical systems are free of the cabinet, allowing visual inspection and repair, while the system is working.

- Made of stainless steel to minimize the heat transfer between incubator and storage.
- Enabling an easy assembly and service of the mechanical modules.

Wet system

- A flow system using a pump for transport of a liquid sample through tubes, avoiding the sample entering a pump.

- A precise dosage of a sample through a dosage needle, using another liquid dosaged by a precision pump, to push the sample through the needle.

- The cleaning of a previous sample from the tubes, using the next sample to remove the previous. An enhancement of this cleaning by introducing air bubbles in the flow of the next sample.

- A dosage head with two dosage needles, allowing dosage of a sample and another liquid, at the drystick at the same time.

- A cleaning of the outside of the sample dosage needle, by flushing liquid from the other needle, with the dosage head positioned in a chamber with a geaometry forcing the liquid from the other needle to surround the dosage needle. A slow controlled retraction of the needle from the cleaning chamber, while the chamber is still filled with cleaning liquid, securing that no cleaning liquid drops remains on the needle.

- A dosage sequence for the dosage needles, resulting in a precise and reproducible dosage on a dry stick. The sequence being dosage at a certain height above the stick, followed by a lowering of the dosage head, letting the dosage needles touch the stick, followed by a lifting of the dosage head, the result being that remaining sample at the dosage needle tip and outside cylinder, is drawed of the needle.

Cabinet

- A cabinet composed of three main elements:
  - An inner cabinet part serving as suspension for the insulation house surrounding storage and incubator.
  - A front cabinet serving as environmental protection.
  - A back cabinet serving as environmental protection for the outer cooling ribs and fans, allowing fresh air to enter the outer cooling ribs.
  - A double enclosure construction, serving as protection against humidity and ammonia, consisting of an outer protection (cabinet front and inner) and an inner protection (insulation enclosures).
  - An arrangement of airguide plate, cooling rib and fan, securing a stable temperature in the incubator room.

Thermostatation sandwich

- A sandwich composed of an outer cooling fin, a peltier element, a heat transfer bridge, an insulating element and an inner cooling rib. The sandwich being produced as a finished unit, ready for assembly through a hole in the inner cabinet and the insulation house. Enabling an easy mounting and dismantling of the cooling sandwich, without risc of damaging the sensitive peltier elements.

DETAILED DESCRIPTION

In the following a preferred embodiment of the present invention will be disclosed with reference to the accompanying drawings.

Explanation of the functional diagram of the Analysis instrument (AI).

A functional diagram of the analyser is shown in figure 1. The main functions are described by:

- A milk sample is apportioned from the sample/transport system (ST) and delivered to the analyzer. The sample is conditioned in order to obtain the correct temperature, transported and applied to the sticks. After the milk sample the diluent is applied to the stick for one stick type. The sticks with the applied sample are incubated while the chemical reaction takes place, and the result is measured. Finally the stick with the sample is transferred to the dispose waste bin.

To realize these main functions some additional functions are preferably needed:

- Magazines of sticks are loaded to a stick storage by the operator, sticks are transported to dosage, sticks are conditioned. Flushing of the flow system with milk is performed between each sample. Main cleaning (CIP) is performed between milking sessions. Diluent is loaded by the operator, stored, transported and added to the sample. Information is read out on a display and information can be entered by the operator into the system by using the user interface (UI) shown in figure 1

In figure 2, a flow diagram of the system in which the analysis instrument is a part is illustrated. A wet and a dry zone are shown, and an indication of the functional modules is illustrated. The functional modules in figure 2 comprises:
Man machine interface (MMI)
Stick storage
Incubator
Sample application
Optics
Storage for used sticks
Electronics
Power sypply
Conditioning of sticks
Storage for fluids

The configuration diagram in Figure 3 illustrates the elements, which are subjected to functional entities for controlling the instruments.
The diagram is divided into four main components.
Host component: External component
Central component
Dosage component

Incubation and Storage component

Description of the host component (External Component) in figure 3.
The Host element represents the Sample Transport system, which shows up to 32 milking point pipelines connected to a multi valve. The milk sample will be transferred through the intake into the mainline in the AI. The communication between the Host and the AI can be done by a ALCOM bit protocol via an HSPI interface attached on the Central board.

Description of the central component in figure 3.
The central component comprises a central board which comprises a central module further comprising means for alarm function, means for light function, man machine interface, computing means, control means.

Description of the Dosage component in figure 3.
The dosage component comprises a dosage board which comprises a dosage module further comprising pipes, a drain and diluent.

Description of the Incubation and storage component in figure 3.
The incubation and storage component comprises an Incubation Storage board further comprising an Incubation Module and a Storage module.

The overall physical realization is shown in figure 4 which illustrates an exploded view of the cabinet with the internal mechanical structure and devices as well as the outer design. The mechanical functions are realized in modules that can be assembled and exchanged with a minimum of adjustments. Most of these modules are mounted to a central beam that gives precise tolerances between the modules.

The Operators user interface
The operator user interface is shown in figure 5 which also shows the front of the AI with the front door open and the exchangeable parts assembled in their positions. figure 6 shows the same view but with the exchangeable parts partly removed from their assembled position.

Mechanical part

Cabinet
The cabinet is illustrated in figure 7 and can be defined as:

- The outer protection against the environment.
- The structure for mounting a central beam on which most of the modules are mounted. The structure for the central beam is housed by the inner cabinet.
- Structure for mounting elements not mounted on the central beam. The structure for insulation enclosures and the structure for central HW board can be housed by the inner cabinet as well.

Overall description of the casing

Figure 8 and figure 9 illustrates an exploded view of the overall description of the casing. In figure 8 the front door, the outer front cabinet, the inner cabinet and the outer back cabinet can be seen, as well as some of the insulation enclosure. Figure 9 shows the same parts but from a different view angle, this time from behind with the outer back cabinet removed so that the cooling ribs on the inner cabinet back side can be seen.

Environmental protection

A central problem in the cabinet design is to prevent humidity and dust from entering the cabinet and at the same time allowing airpassage when temperatures are changing. This has been solved by closing the cabinet as effectively as possible and to pressure release through a valve where humidity and dust can be controlled.

In order to protect the internal parts, preferably a structure having an inner cabinet as structure for the mechanical modules and the hard ware (HW) is used, see figure 4. The internal devices and structures are protected towards the outer environment, by an outer front cabinet shown in figure 4. The only openings into the inner cabinet are at the inlet for cartridges, where a hatch can be opened. The hatch can be a part of the storage/central beam structure, at the stick waste container and at the liquid waste funnel shown in figure 5 and 6. These three openings are carefully designed in order to avoid air penetration when closed.

The outer back cabinet shown in figure 9 serves to protect the outer cooling fins and a fan shown in figure 9 or 12. Air can flow through this part of the cabinet.

The insulation enclosures shown in figure 15 secure a stable temperature and a minimal power consumption for cooling and heating to desired temperatures. They also serve as a moisture barrier together with the outer cabinet.

User interface

A front door gives the user access to the user interface, shown in figure 5 and 6 (keyboard, screen, cartridge load, stickwaste container, diluent container, liquid waste funnel, wet system filter). Furthermore the front door also serves as a double protection for the inner cabinet.

Production and material

The plate parts of the cabinet are made of stainless steel plates welded together. Also other sorts of metals can be used. Other alternative material could be polymers

Inner cabinet

The inner cabinet shown in figures 4, 10 and 11, is welded of stainless steel plates. It serves as structure for the insulation enclosures, the upper beam, internal and external fans, cooling ribs and peltier elements.

A room in the cabinet is reserved for the diluent- and stickwastecontainer, shown in figure 11. This room also gives access to the liquid waste funnel and the wet system filter.

Peltier elements and cooling ribs

The conditioning or thermostatation of storage and incubator is done with at least one peltier element for each room.

The outer cooling ribs are placed in a separate cabinet figure 10, 11 and 12. They could alternatively be placed inside the inner cabinet. A surface treatment of the outer cooling ribs could be necessary to withstand the environment.

The peltier elements, the cooling ribs and insulation between the cooling ribs can be assembled as a sandwich shown in figure 10, in order to be removable as a whole or partly from the cabinet. Gaskets between the outer cooling ribs and the cabinet secure the tightness of the cabinet. The peltier elements are placed in connection with the outer cooling ribs in order to provide a more effective heat transfer from the elements. An aluminium bridge can be used to connect the peltier elements and the inner cooling ribs. The cooling ribs are placed vertical in the back of the inner cabinet, see figure 10, 11 and figure 12, in order to get a short direct transfer of heat from inside to outside. Additional the vertical orientation secures that eventual condensation can be assembled in the bottom of the cabinet and removed.

Fans

A fan for each room and one or two external fans removes the heat energy from the cooling ribs see figure 11 and 12. The fans are constantly running during operation.

Air guide plates

Plates for guiding the heated/cooled air are mounted to the inner cabinet or the insulation, see figure 10,11 and 15. Heat guide elements is a possibility for distributing heat/cold correctly in the rooms.

Consumables room

A room in the left front, see figure 5, contains the diluent container and the stickwaste container. The room gives access for removing and cleaning the wet system funnel and the filter. There are openings from the incubator room for used sticks, funnel, sample tube, diluent tube. The tightness of these openings is secured. Gaskets secure the tightness between the consumables room and the outer front cabinet.

Structure for central beam

A structure serves for mounting the central beam to the cabinet. see figure 4 and figure 10.

Central HW board

The central HW board in figure 3, and the two RIO boards, figure 4, can be mounted to the inner cabinet.

Pressure release valve

A pressure release valve compensating for changing temperatures is necessary.

Connections

A connection box is placed on the back of the inner cabinet, penetrating the outer back cabinet, see figure 9 and 12.

Milk sample inlet tube, signal cable, power cable are connected to the connection box. Milk sample waste could be connected in the same box or in the bottom of the cabinet. Also the connections for external light and alarm preferably passes this connection box. All connections passes the cabinet in IP65 and airtight cable passage components.

It is important to seal all cables to avoid air movements between inner cables and outer cable protection.

Outer front cabinet

The outer front cabinet has openings for the reload hatch where cartridges are loaded and for the consumables room, see figure 5, 6 and 13.

The display and keyboard are mounted directly to the front plate in order to obtain tightness, see figure 6.

The outer front cabinet has IP65 tightening against the inner cabinet backplate and tightening against the consumables room and the frame for the reload hatch.

The outer cabinet can be removed from the inner by releasing locks or nuts in the front plate and pull it towards the operator.

A sensor checks whether the front cabinet is mounted to the inner cabinet.
A thin insulation can be applied by gluing it to the inside of the inner cabinet in order to improve the insulation capacity even further.

Front door

The front door in figure13, has sensors for ensuring that the door is closed, if the front door is not properly shut a signal will alert the operator.
Preferably the hinges, lock and handle are mounted outside gaskets.

Outer back cabinet

The outer back cabinet serves as protection for the outer fan and the cooling ribs, and for mounting the AI on to a wall or another suitable surface. The outer back cabinet is shown in figure 14.
A hole in the outer back cabinet serves as passage for the connection box.
Gaskets secure tightness to inner cabinet. Openings in the bottom and top of the outer back cabinet secures airflow over the cooling ribs figure 12. Damping elements between the mounting brackets and the outer back cabinet can be used in order to lower the impact of possible mechanical vibrations from the surface on which the AI is mounted to.

Insulation enclosures

Figure 15 shows the different insulation enclosures inside the AI, which are necessary to keep the temperature stable.

The temperature in the storage should be kept at 20°C+-3°C, and the temperature in the incubator at 25°C+-3°C. The humidity in the storage should be below 30%RH. The insulation serves to obtain this.

Preferably Expanded polystyrene (EPS) or Polyurethane (PUR) is used as insulation, EPS being easier to obtain UL approval of, with acceptable insulation values.

If EPS are chosen the cabinet will be manufactured by injecting EPS pellets into a mould and applying steam. This will give an insulation house that should be mounted to the inner cabinet

PUR could be injected between two shells, the outer shell could be the inner cabinet.
Obtainable insulation value for EPS is 0.033 W/mK (type F495). This gives insulation thickness of approximately 35 mm for storage. For the incubator the temperature used to be 37°C. For this temperature 20 mm were sufficient. 30-35 mm will probably be necessary for 25°C.

Gaskets between the peltier/cooling ribs sandwich and the insulation are necessary.
Gasket between the reload hatch frame and the insulation are necessary.
The top insulation shown in figure 15 can be lifted to give access to the dry and wet system. A gasket between the top insulation and the insulation enclosure is necessary. The

top insulation could alternatively be made of two parts allowing separate access to incubator and storage.

A lock system between the top insulation and the insulation enclosures is needed.. A sensor will detect whether the top insulation is present or if it has been removed. If it has been removed and not put back into place a signal will alert the operator.

Upper beam

Function
The central beam shown in figure 4, serves as structure for mounting storage disc, incubator disc and their drives and sensors, stickmover, wet system, optical reader and frame for reload hatch. The idea with the upper beam, figure 16, is to mount the elements with precise tolerance demands to a rigid structure as close as possible to their interacting areas.

Strategy of position-sensing for turntables

The position-sensing enables the synchronization of the virtual position in software (SW) and the physical position of turntable. The turntables are divided into positions, figure 29 and 30, the incubator has stick slots and the storage has cartridge slots. Each position is provided with a fane that interacts with a photointerrupter by interrupting the light beam. The flank of any fane is used for zero-setting the position counter. The flank is received a number of steps before the correct positioning, the so-called offset. The offset parameter can, if needed, be adjusted during assembly and test, to take up manufacturing tolerances.

The power-up and hard-restart strategy, described in the table "Strategy at power-up and hard restart" below, states the need of "near right position"-sensing. This is because the start-up sequence of synchronization does not allow the rotation of turntables before it is ensured that the stick-mover is not engaged with a turntable. An additional photointerrupter is used together with the home-flank sensing photointerrupter. Each photointerrupter is positioned at a fane, their mutual distance being smaller than the mutual distance between the outer flanks of the two fanes. The condition that both light beams are interrupted is therefore only at "near right position". The denomination "near right position" is used, as the precision of the position is much poorer than when a flank is used.

The slots of the incubator are genderless/anonymous. Any fane can be used for home and there is no need for absolute positioning e.g. a "per revolution sensor".

The cartridge positions of the storage turntable are unique as there is colorimetric, lateral flow and desiccant cartridges. Any fane can be used for the home-flank and the bar-code

reader for the identification of the cartridge at used fane, thus enabling fully synchronization without the need of a "per revolution sensor".

Strategy at power-up and hard restart

5

Stick-mover feed-back					
Sensor I	Sensor II	Position of stick-mover pawl	Storage "near right position"?	Incubator "near right position"?	Action
1	0	At home	True and false	True and false	1. Initialise Storage. 2. Initialise incubator
1	1	Maybe in a cartridge	True	True	1. Stick-mover forward until in incubator. 2. Reverse stick-mover to home. 3. Init. Storage. 4. Init. Incubator.
			True	False	1. Init. Incubator. 2. Stick-mover forward until in incubator. 3. Reverse stick-mover to home. 4. Init. Storage.
			False	True and false	1. Reverse stick-mover to home. 2. Init. Incubator. 3. Init. Storage.
0	1	In guide-way	True and false	True	1. Stick-mover forward until in incubator. 2. Reverse stick-mover to home. 3. Init. Storage. 4. Init. Incubator.
			True and false	False	1. Init. Incubator. 2. Stick-mover forward until in incubator. 3. Reverse stick-mover to home. 4. Init. Storage.
0	0	In incubator	True and false	True and false	1. Stick-mover reverse to home. 2. Init. Storage. 3. Init. Incubator.

Operation mode of turntables

Function of the drives

To index the incubator and storage turntables in order for both to be positioned correctly, and thereby allowing a stick to be transferred from storage to incubator, both drives are identical.

Applied solution

figure 16 shows a view over the driving assembly. The drive consists of a 200 increment stepper motor with a press fit pulley, a toothed belt and a bearing assembly comprising shaft with pulley, two sealed ball bearings and a machined bearing house secured to the upper beam. The stepper motor is bolted to a mounting plate, and the center distance is fixed, e.g. no adjustment necessary.

For a specific embodiment the Data and specifications is presented below

Drive power needed:	max. 2W
Ratio:	9:1
Motor pulley:	15 teeth
Timing pulley:	135 teeth
Belt pitch:	2 mm
Belt profile:	MR2 x 6mm(width)
Resolution:	0,04°(~0,1mm on the incubator disc/storage outer perimeter)
Intended indexing angle:	incubator 8° storage 18°
Intended time for 180° index:	incubator 2.5s Storage 4.5s

Dosage Component

Mechanical part

Dosage flow system illustrated in figure 17, comprises a dosing head, pumps, a bubble detector, a drain, a Multi Valve, valves and pipes.

Figure 18 illustrates the dosing station with the drain. The drain can also be seen in figure 19.

Figure 20 and figure 21 shows two different ways of dosing milk onto a test stick. In figure 20 the milk is applied from approximately 1-3 mm height. In figure 21 the mouthpiece is lowered in order to contact the test stick with the milk, by doing this the milk is applied onto the test stick..

Incubation Component

Mechanical part

The main mechanical part is an incubator disc comprising a number of slots. The incubator disc is shown in figure 24,.

Function

The incubator disc is necessary for positioning, keeping and guiding the sticks in place during the loading, dosing, incubation, reading and removal steps of the analysis process.

Number of incubator slots

The number of slots is 45,these are divided into the different sectors as described below:
Slots 1 through 4: Is used for temperature conditioning of the sticks. Between these positions the temperature of the sticks is raised from 20°C to min. 30°C by using a forced flow of the 37°C incubator chamber air. The IM temp altered to 25°C.
Slot 5: is for dosage of milk onto the test sticks.
Slots 5 through 44: is for incubation of the sticks. The indexing interval is 8 seconds, as each sample needs to be taken from ST every 24 seconds, in average, and 3 tests, in average, is needed from each sample. The specified time of incubation is 300 seconds and the number of slots of incubation is therefore 38.
Slot 44: is for the reader.
Slot 45 is allocated for physical clearance between reader and stick-mover.

Applied solution

The incubator disc can be made of 3 mm stainless steel. The manufacturing of the disc can be done by a combination of laser cutting and punching. The disc has 45 places, which can be used for both lateral and colorimetric sticks.

To ensure fixing of the sticks, an injection moulded incubator slot has been mounted for each incubation place, this is shown in figure 23.

When the stick is transferred from storage, the upper side of the stick meets the bottom of the incubator disc.

The incubator slot has lead-in to obtain tolerances, see figure 22. The slot also functions so as to guide the wings of the sticks when the sticks are transferred onto the slot.
Furhtermore the slot has been supplied with a built-in lock to maintain the stick, when the disc is rotating or the apparatus is influenced by external conditions.

Simultaneously, the lock makes sure that the stick is positioned precisely against the disc, when loading or unloading is taking place.

The incubator slot has been fixed to the disc, shown in figure 23, by means of thread shaping screws. Furthermore, the incubator slot has fanes for detection of position. An incubator slot has two fanes, where the other one can be used for one per revolution sensor.

Data and specifications

Disc:
3 mm stainless AISI 304.
Manufactured by laser cutting and stamping.
Weight: 640 g.
Slot:
Injection moulded in POM.
Changing the length of one of the ejector pins can make a variant with two fanes for a "per revolution sensing"
Volume: 550 mm^3
Weight: 0,77 g.
Figure 24

Waste full and obstruction detection

Function of the detection

The function of the detection device serves several purposes, firstly it provides detection of full waste container, in case it is not completely emptied by the operator, secondly the device is able to dissolve an obstruction in the chute, and the device can also function as an airlock between incubator and the surrounding environment.

Applied solution

Different solutions have been taken into consideration, but a purely 'mechanical' solution gives the highest degree of confidence. The design intent, which is illustrated in figure 25, is to let a fane, driven by a small DC gear motor perform a sweeping motion across the gap between chute and waste container, every time a stick is transferred from storage to incubator. The shaft of the gear motor has a crankshaft connected to a pretensioned spring. As the shaft only rotates in one direction, the spring will pull the fane positively to a stop when closing, and push the fane when opening motion is called upon. Should an obstruction occur, the fane will stop at it, and the spring will allow the crankshaft motion to continue, until the fane is moved away from the obstruction, thereby tripping the 'airlock open' sensor. Sensors (photo interrupters) at each end of the fane's travel will detect, if an obstruction has taken place, and notify the operator. A sensor detects if the waste container is in place, and resets the used stick counter.

Function during normal behaviour:

1) The number of used sticks are monitored and accounted for by the AI.

2) When xx units of sticks have been processed, the operator is notified about the fact that the waste container should be emptied soon, for instance when the milking session is completed, as there is enough space for additional used sticks, to complete a milking session.

3) The operator empties the waste container, and as he replaces it correctly, the used stick counter is reset.

Function during unusual behaviour (case1) (1 through 2 as in normal behaviour):

3) The operator does not empty the waste container completely, and sets it back.

4) The 'waste container in place' sensor resets the stick counter.

5) The waste container will now be filled, before xx number of sticks is reached, and sticks will protrude up through the airlock between chute and waste container.

6) The level detection senses 3 out of 3 consecutive times that an obstruction has occurred.

7) A beacon lights up to alert the operator.

8) Sticks will no longer be transferred, but sticks already transferred to the incubator will be processed (milk will be dosed, and the reader will collect the data).

9) The operator comes to the AI, and empties the waste container. As he opens the front cover in the outer cabinet, the fane sweeps away from the gap, thereby permitting any jammed sticks to drop into the container.

10) As the empty waste container is returned to its position, the stick counter is reset as the 'waste container in place' sensor is tripped. Behaviour can restart at 1).

Function during unusual behaviour (case 2) (1 through 2 as in normal behaviour):

3) The operator does not react at all to the warning.

4) When the waste container is filled with xx+yy sticks, the pattern will be as from 6) through 10).

Control strategy of waste level detection			
Action	Sensor 1 Airlock closed	Sensor 2 Airlock open	Sensor 3 Container in place
At stand-by	1	0	1
At stick transfer into incubator and/or stick to waste, the DC-gear motor is turned on until S2 is interrupted at which point the motor is turned off.	0	1	1
After a short delay the motor is turned on to return fane. When S1 is interrupted the motor is turned off.	1	0	1
In case there is an obstruction (a stick in chute) S2 will be interrupted instead. Is S2 interrupted 3 times the motor is turned off at S2 interrupted to leave the airlock chute open. The alarm is turned on to call operator to empty waste.	0	1	1
Power-up: S1 interrupted - no action needed. If not interrupted the motor is turned on until it is.	-	-	1

Thermal conditioning of stick

Function of the thermal conditioning

The sticks are kept in storage at 20°C, before they are transferred to the incubator, where they must achieve a temperature of at least 30°C, before dosing in order to avoid milk fat depositing on the sample. Since the temperature inside the incubator module is 37°C, one way of achieving the heat-up of sticks, would simply be to let them cure from slot number 1(transfer slot) to the dosing slot. Tests have shown that for a colorimetric stick, it takes ~40s to rise from 20°C to 30°C by natural heat convection, while it only takes ~15s when forced convection is applied by means of a small fan. If natural convection was to be used, it would require 6 spaces, and dosing would take place at slot number 7. The same test on a lateral stick showed that 30°C could be reached within 20s with the fan. To reduce the size of the incubator (and therefore the size of The Merkur Analyser), forced ventilation has been chosen. As the total elapsed time for a complete revolution of incubator is 5min(300s), 4 spaces will give sufficient time (~27s) for the temperature to rise.

Applied solution

A small fan integrated in the upper beam, illustrated in figure 26, directs the airflow towards the 4 slots that lies between transfer slot and dosing slot.

Data and specifications:

Description:	DC brushless fan
Dimensions:	50x50x10
Rated voltage:	12V
IP:	25
Air flow:	7.3cfm(at 1.8mm H_2O)

Storage component

Storage turntable

Function

The storage turntable stores the cartridges, loaded by the operator, and presents them to the stick-mover that sweeps out the DS from the top of the cartridge.

Storage must:

Have 14 CS-cartridges.

Have 3 LS-cartridges.

Have 1 desiccant-cartridge.

Enable renewal of cartridge through reload hatch.

Enable thermal conditioning of sticks.

Enable reading of cartridge bar-code label.

Present cartridge for stick-mover.

Enable "dry-run" of stick-mover, so that it can empty incubator without the need of inserting a fresh DS.

Applied solution

It has been decided that the storage must be a turntable carrousel. This is illustrated in figure 27.

In the carrousel each cartridge is stored in a keeper, which is a box open in the top. The keeper is hinged in the bottom so that it can be swung out to present the cartridge to the operator in a horizontal position, illustrated in figure 27 and 31. In the upright position the keeper is locked in place by a pawl. The keeper is forced outwards by a spring placed at its hinge. When the reload hatch is opened the keeper-pawl is actuated to release the keeper.

The carrousel is a squirrel cage construction - two discs interconnected by spacer rods, illustrated in figure 31. The upper disc is equipped with a flange, which is bolted onto the shaft of the drive. Upper disc is cut out in a pattern forming places for the cartridges that stick out of the top of the keepers. Each cut out is flanked with a spring-loaded pawl arrangement that is locking each keeper in the vertical position. The bottom disc is ring-shaped and supports the hinges and springs for the keepers.

Please refer to section "Cartridge" for the interaction between Cartridge and keeper/storage.

Keeper pawl assembly illustrated in figure 31, consists of a involute shaped pawl, that has a pin pressed into it. The pin pivots in the support that also houses the pre-tensioned coil spring.

At each keeper the upper disc have a fane providing optional feedback when interacting with photo-interrupters. One fane is prolonged to provide a "per revolution" sensing. Sensor and prolonged fane could be omitted when the Bar-code reader is integrated, as it identifies the cartridges.

Function sequence

Removing used cartridge and loading full cartridge:

When the reload-hatch illustrated in figure 5, is open a keeper is presented through the hatch opening.

The operator pulls the used cartridge out of the keeper and insets a new one.

Closing hatch and locking keeper in carrousel:

The operator closes the reload-hatch that is hinged in the bottom. The reload-hatch pushes the keeper that also swings up. The keeper can be seen in figure 27 and 31.

During the closing, a pawl on the reload-hatch, pushes the cartridge further down into the keeper, against the force of the pusher spring placed in the bottom of the keeper. This allows a protrusion on the back of the cartridge to pass under the upper disc, illustrated in figure 32 and 36. When this has occurred the pawl retracts, cartridge jumps up until the mentioned protrusion rests against the underside of the upper disc – making the chain of tolerances as short as possible, ensuring that each cartridge is leveled in respect to the stick-mover and tunnel.

When the reload-hatch is almost closed, the spring loaded keeper-pawl pulls the keeper the rest of the way. This leaves clearance between the reload-hatch and keeper, 2 ± 1 mm. The backside of the cartridge rests against the edge of the cut out in the upper disc – keeping the position tolerances low.

Opening the reload-hatch and releasing keeper:
The AI opens the reload-hatch as it releases a pawl locking the reload-hatch in the closed position.

The reload-hatch interacts with an arm that actuates the keeper pawl, releasing the keeper when the AI opens the reload-hatch.

When the keeper is released, it swings out and rests against the partly opened reload-hatch. The operator swings the reload-hatch down, while the keeper follows its motion, until the reload-hatch rests against a stop in a horizontal position, see figure 6.

Keeper pawl – interacts with a protrusion on the side of the keeper shown in figure 30 and 31

Data and specifications

Upper and lower disc
Made in seawater resistant aluminium - 4 mm thick.
Function models manufactured in a combination of laser cutting and revolver stamping. Revolver stamping with two custom stamping tools at low volume production. The custom tool stamps out the complete contour for one cartridge position – one tool for each size of cartridge. High volume production is done in a stamping tool making the complete contour, see figure 31.

Flange
The flanges in the functioning models are turned and milled in aluminium. However composite injection moulding could be more profitable forhigh volume production. The flange can be redesign since the drive also can be placed on the upper beam, instead of on a lower base plate

Spacer rod
The spacer rods in the functioning models are turned in aluminium.
For higher volume manufacturing they may be turned in glass fibre or reinforced composite.

Screws
All screws are of the thread forming type, reducing the cost of parts as simple drilled or stamped holes are used. The formed thread is the Metric-standard, meaning that standard M-screws can be used in the need of replacement.

Keeper pawl assembly

Keeper pawl, shown in figure 31, has for the functioning models been manufactured by laser cutting of aluminium plate – 2.5 mm thick. To improve function and costs the manufacturing method can be changed to either metal sintering or composite moulding.

Springs

Springs are made of stainless steel.

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Plunger

Function

The plunger, shown in figure 32, exerts an upward force on the sticks in the cartridge to move the stack of sticks up when a stick is removed, presenting next stick for the stick-mover. The plunger is forced upwards by two springs.
The plunger has to supply the bottom with an upright force constantly to secure its functions.

Applied solution

The plunger has been designed in a way that it smoothly fits into the bottom, see figure 32.
The only integration for the cartridge is the vertical guide way in cartridge. The plunger is unlocked as much as possible at all other integrations.
The plunger gets its power from the two springs, which have been placed in the sides and are guided on Ø 3 mm stainless stiffeners shown in figure 33 and figure 39.
The springs in the Lateral Cartridge (LC) shown in figure 33, are heavier than in the Colorimetric Cartridge (CC) shown in figure 39, due to a larger need for force for increased friction and weight. The heavy springs has a built-in length which is slightly larger, and which is possible due to the fact that the 50 sticks in the LC take up less space compared to the 100 sticks in the CC.
The LC plunger shown in figure 32, has been made by milling POM due to very good friction properties. The CC plunger also shown in figure 32, has been made of SLS due to the complicated geometry. The height of the plunger has been precisely defined and has been clearly oriented in the keeper.
Both items can also be injection moulded.

Storage keeper

Function

The function of the keeper is to maintain and position the cartridge in the storage. The positioning has to be adjusted to the height of the stick mover. Also the cartridge has to be

oriented radially, so that the stick can be guided in a direct and straight line to the incubator.

Applied solution

The keeper itself has been made as an item in SLS. In the keeper the stiffener of the plunger has been mounted by means of circlips. Furthermore, a spring loaded bottom stop has been mounted to secure the cartridge is being guided towards the upper storage disk. This is shown in figure 32 and figure 58. Internal lead-in in the keeper and the cartridge and external lead-ins in the plunger ensure easy mounting of the cartridge, see figure 32, 34 and 35.

When the cartridge has come ¾ way down the keeper, it meets a snap-lock, which locks the cartridge in proportion to the keeper. In the snap-lock there is approx. 5 mm free space, which is used for the movement in reload and in the upper storage disc.

Radially the cartridge is oriented partly by minimal air between the front of the cartridge and the upper storage disc, and partly by two projections on the cartridge, which have minimal air for the periphery of the disk. When the cartridge is being mounted by means of reload, it is being pressed down to the bottom stop of the keeper shown in figure 33. When the cartridge is in storage, reload loosens up, and the cartridge is being positioned in a given height, which has been adjusted by the tap on the cartridge. In this way, it will have the smallest possible tolerance chain in relation to the stick mover.

Data and specifications

Function models made of SLS. Later on: injection moulded in POM as two items snapped or welded together.

Physical data, LC keeper:
Volume: 76.500 mm^3
Main dimensions (L x W x D): 180 x 21 x 85 mm

Physical data, CC keeper:
Volume: 31.800 mm^3
Main dimensions (L x W x D): 180 x 21 x 30 mm

Conditioning humidity and ammonia content in storage chamber

Function of the conditioning

The chemistry in the sticks is sensitive to humidity (H_2O) and ammonia (NH_3), both represented in a stable environment. When the operator changes cartridges, a certain amount of air exchange to the ambient surroundings will take place, and chemistry will therefore be exposed to the above-mentioned components. The required levels are that

relative humidity is to be kept below 30%, and ammonia is to be kept below 3ppm. Stable environment in particular can be up to 100%RH and 20ppm NH_3 at 45°C.

Applied solution

A 4A molecular sieve, see figure 38, with the ability to adsorb both ammonia and water gives the best overall solution, since it retains its ability to adsorb water molecules over a much wider spectrum of temperature than other desiccants. The best way to gain access to the desiccant, is through the reload hatch, and the best overall solution is therefore to allocate a place in the storage turntable to a desiccant cartridge. The physical dimensions of this "desiccant cartridge" are the same as the lateral stick cartridge, as it gives the largest volume (=high capacity) and surface (=fast response). A desiccant cartridge would consist of a perforated lateral stick cartridge with an app. 80g. of desiccant in pellet size 1-1.6mm. As with the 'stick' cartridges, desiccant cartridges are delivered individually in sealed bags. Change of a desiccant cartridge is similar to the change of a lateral cartridge. Airflow through the desiccant is achieved by letting the storage carrousel slowly rotate, when no sticks are required.

Control strategy:

The humidity level is monitored in the AI, and exchange of desiccant will be based upon a time/humidity profile: as the operator is notified about the need to change a lateral or colorimetric cartridge, the AI checks two parameters:

- Actual humidity level: should it exceed 25%* for instance, the desiccant cartridge must be changed.
- Time elapsed since last change: should it exceed 45 days* for instance, the desiccant cartridge must be changed.

Data and specifications:

Nominal pore diameter:	4 angstroms(0,4nm)
Type of crystal structure	cubic
Amount of desiccant:	~ 80g
Bulk density:	
Nominal consumption (estimated):	1 cartridge/month
Worst case consumption (estimated):	1 cartridge/2 week*
Ammonia capacity:	see next slide
Water capacity (at 55%RH@20°):	22%wt
Water content (as shipped):	1,5% wt.(max)

*: Assuming a total exchange of air to an environment with 100%RH and 20ppm NH_3 at 45°C. Figure 38

One set-up, is a lateral cartridge with stamped or drilled holes and loaded with desiccant, figure 37, in a permeable (Gore-Tex) bag. The moulded cartridge will be bigger and perforated with small holes. This gives 2 benefits:

- Higher capacity as a result of higher volume of desiccant, therefore longer exchange rates.

- Faster response as the water and ammonia molecules would not have to pass the primary barrier, namely the material of the bag, and thereby minimising the exposure to the chemistry.

Stick mover

Function
The stick-mover transfers the stick from the storage to the incubator disc, see figure 39.

Applied solution
The stick-mover shown in figure 39 and 40 and 41 consists of:
A pawl that manipulates the stick. Guided in a coulisse that lifts the pawl over the cartridges when the stick-mover is reversed. The pawl is hinged and forced down by a spring.
A linear guided slide on which the pawl is hinged. The slide is provided with a teeth rack and fanes for position sensing.
A gearwheel that drives the slide.
A 48 PM-stepper motor with a pinion that drives the gearwheel with a 3,33:1-ratio.
Two photo-interrupters sensing the fanes on the slide.
A housing providing linear guiding of slide, coulisse guiding of the pawl, support of photo-interrupters and a tunnel in which the stick is guided between storage and incubator.
The stick-mover can also be equipped with air-sluices to reduce airflow between incubator and storage chambers.

Function sequence
The function sequence is illustrated in figure 41.
The pawl rests in the reversed position, the Home-position. The pawl is lowered. The cartridges on the turntable can pass by the tip of the pawl, as it is positioned close to the center of the turntable.

When the desired cartridge is positioned under the stick-mover, aligned with the stick tunnel, the motor is activated to advance the slide. The slide forces the pawl forward. The pawl enters the lower track of the coulisse.

The pawl meets the ramp placed on the top and back of the cartridge. The ramp forces the tip of the pawl to flex upwards, which eliminates misalignments and levels the tip of the pawl in relation to the stick.

The tip of the pawl engages the end wall of the stick. The end wall of the stick has a shelf-like protrusion matching a cutout in the profile of the tip of the pawl, preventing the pawl to slip of the stick.

The stick is pushed out of the cartridge, passes over the gap (2±1 mm) and enters the tunnel, assisted by leading-in chambers.

When stick and pawl have entered the tunnel the storage turntable is allowed to turn to present next cartridge. The stick-mover may be stopped in this position to await the indexing of the incubator turntable.

The slide is advanced further on and the pawl leaves the coulisse and flipping up a flexible track-changer.

The stick passes the gap and into the slot of the incubator and advanced to the intended position. The fresh stick pushes used stick out of the slot. The used stick falls into the waste container.

The slide is reversed and the tip of the pawl slides of the stick.
The pawl enters the coulisse – being guided into the upper track by the track-changer. The pawl is passing over the cartridge, thus allowing the turntable to rotate.
The slide is returned to home where the pawl is lowered as the upper and lower tracks are connected at this position.
Motor is turned off and cycle is complete.

The motor is driven in ½-step mode to enhance the resolution. Micro step modes are not used as PM-stepper motor don't perform precisely in these modes, as the detent/motoring-ratio is high and the BEMF isn't sinus-shaped.

At standstill in the home position the motor is turned off to prevent heat generation. At other points of standstill the current is reduced to about 50 %, with reduces the heat generation with 75%. The synchronism is maintained.

When advancing from home position a digital flank is received from the sensing of the home fane. The flank is used for zero-setting the position counter. The slack of the drive train is taken up as advancing begins and the position counted is only precise when mowing forward. When reversed the slack shifts direction, meaning a longer virtual movement is necessary to return to home.

Data and specifications

Step per rev.	48	PPR	7,5 PM-stepper motor
Microstep	2	µstep/step	Using ½-step mode
Needed resolution	0,098	mm	
Available dL per rev.	9,42	mm/rev.	
			Engaging linear tooth rack on stick-mover slide
PitchDiameter toothwheel	10	mm	
Perimeter toothwheel	31,4	mm/rev.	
Neded i	3,33		
Z motorpinion	12		

Z gearwheel	40,00	Bigger wheel on above mentioned tooth wheel

Reload hatch

Function
The reload hatch enables the renewal of cartridges by the operator. Together with the storage turntable it presents used cartridges to the operator that renew the cartridge. Enable secure and easy renewal of cartridges in corporation with the storage turntable.

Furthermore it can be equipped with gaskets towards the storage insulation, internally between hatch and frame and also towards the inner cabinet in order to minimise entry of ambient air into the storage chamber

The reload hatch also comprises sensing means in order to be able to secure that the hatch has been correctly closed and that it is in the closed position.

Function sequence
Renewing cartridge
When the reload-hatch, shown in figure 5 and 6, is open a keeper is presented through the hatch opening.

The operator pulls the used cartridge out of the keeper and insets a new one.
The reload-hatch is preventing the keeper to swing up during the insertion. Done with the means of protrusions on the keeper that has entered hooks on the reload-hatch during the opening of the reload-hatch.

The leading in of the cartridge and prevention of accidental twisting of the keeper plunger is assisted by arms that are swung up on both sides of the top of the keeper during the opening of the reload-hatch.

Closing hatch and locking keeper in turntable
The operator closes the reload-hatch that is hinged in the bottom. The reload-hatch pushes the keeper that also swings up, shown in figure 6.

During the closing, a pawl on the reload-hatch, pushes the cartridge further down into the keeper, against the force of the pusher spring placed in the bottom of the keeper. This allows a protrusion on the back of the cartridge to pass under the upper disc. When this has occurred the pawl retracts, cartridge jumps up until the mentioned protrusion rests against the underside of the upper disc – making the chain of tolerances as short as possible, ensuring that each cartridge is leveled in respect to stock-mover and tunnel.

When the reload-hatch is almost closed, the spring loaded keeper-pawl pulls the keeper the rest of the way. This leaves a clearance between hatch and keeper, 2 ± 1 mm. The backside of the cartridge rests against the edge of the cut-out in the upper disc – keeping the position tolerances low.

Finally a pawl locks the reload-hatch and a gasket seals against the reload-hatch casing.

During the closing the reload-hatch pushed the arm, that released the keeper pawl when the reload-hatch was opened, is returned to normal position to allow the pawl to lock the keeper.

A photointerrupter sense that the reload-hatch is closed and the turntable is allowed to rotate.

*Opening reload-hatch and releasing keeper.*The AI opens the Reload-hatch as it releases the pawl locking the reload-hatch. The pawl is actuated by a dc-motor equipped with a gear. To release the pawl the motor is energized to turn a eccentric pushing the spring loaded pawl. The motor is stopped when it returns to home sensed by a fane on the eccentric and a photointerruper.

The reload-hatch interacts with a spring loaded arm that actuates the keeper pawl, releasing the keeper when the AI opens the hatch.

When the keeper is released, it swings out and rests against the partly opened reload-hatch. The operator swings down the hatch, while the keeper follows its motion, until the hatch rests against a stop in a horizontal position.

During the motion the keeper and hatch are locked together and a gate is swung up at the top of the keeper as previously mentioned.

To facilitate opening of the reload-hatch during repair and service the pawl can be released by sticking a small rod through a hole.

Control strategy.

HW integrates to two photointerrupters and one dc-motor. The motor is used unidirectional e.g. no shift of polarity needed.

One photointerrupter monitors if the reload-hatch is closed. The light beam is interrupted when the reload-hatch is closed. The storage turntable is allowed to rotate when the reload-hatch is closed.

To open the reload-hatch the dc-motor is energized. The motor is turned off when it returns to home sensed by a fane and a photointerrupter. At home the light beam is interrupted by the fane.

Dry Stick frames

Function

The stick frames shown in figure 42 and 43 provides handle-ability to the chemistry pad. The path of handling from production to waste is:

- Frame is manufactured by injection moulding.
- Pressing the pad into the frame assembles chemistry pad and frame, now forming a dry stick [DS], shown in figure 42.
- DS are stacked in appropriate numbers and inserted in cartridge. A formed sheet of stainless steel is inserted under the stack forming a no-return floating bottom, securing the stack at any stack height, shown in figure 57.
- Cartridge is wrapped in protecting seam-welded bags, packaged in boxes and put on stock, while kept cold at 5°C.
- Box is transported and distributed to the end-user, still kept cold.
- Box is received by end-user and put in refrigerator.
- A single cartridge is retrieved from box and brought to AI, inserted in AI-storage, after removal of bag, to replace an emptied cartridge.
- The storage temperature is kept at 18°C and the humidity is kept below 30 %RH.
- The storage turntable presents the cartridge to the stick-mover when a DS of that specific constituent is desired.
- The pawl of the stick-mover sweeps out a DS from the top of the cartridge, through a tunnel between storage and incubator turntables, and into a slot of the incubator, shown in figure 41. The DS is ejecting a used DS from the slot, when inserted. The used DS falls into a waste container, which is emptied by the user at appropriate intervals.
- As a DS is removed from the cartridge the stack jumps up to present next DS, by means of springs located in the storage. These springs were compressed at the insertion of the cartridge.
- The incubator turntable has 45 slots, indexing one slot each ~8 sec, presenting the DS to the dosage module and reader. The slots forms a guide way, with integral springs pressing the DS against the underside of the incubator, reducing the number of elements in the chain of tolerances.
- While indexing from point of stick-insertion to point of dosage, the temperature of the DS is raised to minimum 30°C, by forcing a flow of 37°C warm storage air to pass over the DS. A DS temperature of 30°C is desired to prevent the milk-fat from changing properties when dosed onto the chemistry. Position 1 through 4 is allocated for warming the DS.
- At position 5 the DS is presented to the dosage-module. The dosing head is formed by needle-tubes or the alike, see figure 18 and 20, which are brought in contact with the chemistry while the volume of milk is dosed. In case of a lateral flow stick [LS] for progesterone a volume of thinner solution is dosed simultaneously.
- In the course of indexing from point of dosage to point of reading the 5 minutes of incubation takes place.

- At the reader the DS is presented and a picture is taken, whilst illuminated with the appropriate wavelength.

The chemistry has two formats, lateral flow and colorimetric:

- The lateral flow chemistry consists of a bottom foil with nitrocellulose and glue on which dosage, reaction and suction fiber pads are placed. A tape is placed on top, except at the dosage area. The chemistry is 5 by 60 mm and up to 1.6 mm high. The position of the reader-line is approximately in the middle. At the moment it is uncertain whether it is 35 mm or 25 mm from the leading edge.
- The colorimetric chemistry is formed by a 5 by 5 mm fiber-pad. At the moment the pad is expected to be 0.34 mm thick.

Applied solution

Material.

- Polystyrene [PS] has been chosen as it has a low cost per volume and a high stiffness modulus. Furthermore it has a high surface tension towards milk, higher than Polyethylene [PE], reducing the risk of the milk seeking out in the gap between frame and chemistry, shown in figure 45.

Manufacture of frames

- The frame is injection moulded. The geometry can be realized in injection tooling, without complexity e.g. separately moving cores etc. Due to the waste numbers needed, the production tooling will have several cavities – maybe as many as 64, and will utilize hot-runners and micro injection-nozzles. The tooling produce no runners and inlet-parts, meaning that there is need to separate and recycle scrap.
- The point of injection is placed in an indention of the geometry to allow some degree of undefined geometry, see figure 46.
- The ejection pins are slightly prolonged, 0.05 mm, so that wear and tolerances can be taken-up without causing protrusions on the frame.
- The stick assembling equipment checks each frame for faults, e.g. dimensions exceeding tolerances and incomplete geometry, and expels faulty frames. This could be done utilizing vision systems and/or laser grids.

Assembly and securing chemistry

- The chemistry is mounted in the frame simply by a pressing motion with an appropriate shaped plunger. No-return hooks placed on the walls of the frame secure the chemistry by positive engagement, shown in figure 47.
- The bottom plastic foil of the lateral chemistry flips under the hooks, although it has cut/deformed to some degree. Frame were realized in soft tooling and assembly of chemistry carried out. It was found that the chemistry at the reader-line did not relate to the bottom of the frame as it bended, which affects the focus/precision of the reader. Therefore rib-protrusions are added, which have a

transversal distance smaller than the width of the chemistry, thus retaining the pad.

- The colorimetric fiber pad is partly formed around and under the hooks, thus retained.
- The first colorimetric frame, that were designed and produced, had the chemistry inserted from underneath. This design presents the top of the chemistry with less tolerance of the level, has a higher flexibility regarding different/changing pad thickness and less critical retaining function, as the hooks have a better leading angle. The design was changed to the present as the concept of dosage has changed from non-contact to positive contact of the needles to the chemistry, which calls for support from underneath of the pad.

Geometry of frames:

- The design of the frames aim to have:
- Lowest possible cost
- Ease of automated production
- High reliability of AI – avoid malfunctions and influence of the precision of measurements
- Small physical dimensions
- Ease of disposal
- Lowest possible environmental impact
- Ease of development, same design paradigm for both frames
- Same level of dosage for both DS
- Same level of reading for both DS

Geometry relations:

- All three sides of the wings relates to stick-mover tunnel guide way, incubator slot and disc.
- Upper surface, sides and end surfaces of wings relates to cartridge.
- Top, bottom and ends of frame relates to other frame in cartridge and at ejection of used DS from incubator slot.
- Bottom relates to no-return floating bottom-part of cartridge.
- Withdrawn end-walls relates to stick-mover pawl.
- Cavity and hooks relates to chemistry.
- Frame relates to waste chute, waste full detector and waste container.
- Frame presents chemistry to dosage module and reader.

The overall height, 2.5 mm, of both frames is determined by the LS, as the chemistry is thicker - at this point of time 1.6 mm. The floor of the LS-frame is 0.6 mm thick, leaving a clearance of 0.3 mm from the top of the frame to the chemistry. The stack-height of the LS is the full 2.5 mm. The stack-height of the CS is reduced to 1.4 mm, by reducing the thickness of the frame body, utilizing the thinner chemistry.

The wings of the frame, shown in figure 48, allow the DS to be guided in the stick-mover tunnel and incubator slot. The guide ways are formed like [ ]-tracks, 1 mm high and 0.8 mm wide.

The stick-mover pawl pushes the stick on its end-wall. The end-wall has a shelf-like protrusion that engages with the stick-mover pawl, preventing it from sliding of and over. The wings are extended beyond the end walls of the frame. This makes room for the stick mover pawl when the next DS jumps up in the cartridge when a stick is swept out. The design of the frames is illustrated in figure 49 and figure 50.

Dry stick cartridge

Function

It is important that colorimetric as well as lateral sticks are guided securely and that they are as easy to handle as possible all the way from production until use in the apparatus. The vertical guidance has to be so robust that the sticks are not erroneously oriented, before they are taken out of the stick mover horizontally. It is necessary for the cartridge to be designed in a way that enables the stick mover to run into an integration surface and be presented to sticks in the same way each time.

Under production, transportation and handling the cartridge with sticks, the cartridge has to be able to withstand all possible ways of handling, which may include pushes, strokes and even drops, but which must not make the sticks be erroneous oriented. The LC (lateral cartridge) contains 50 sticks, and the CC (colorimetric cartridge) 100 sticks.

Applied solution

Due to various physical designs of colorimetric and lateral sticks, two types of cartridges are available. The two types are called Colorimetric Cartridge [CC] and Lateral Cartridge [LC], respectively. Apart from the depth, the two cartridges are almost identical. The two cartridges can be seen in figure 51 and figure 52.

A cartridge consists of two injection-moulded shells, which have been ultrasonic welded together. The shells are made of impact modified PS, which has been chosen due to the favourable price and the mechanical qualities desired, both regarding strength/stiffness and welding.

In the following, the cartridge and the parts, which have integration for the cartridge, are described more closely and will apply for both the CC and the LC.

Ultrasonic welding

- A cartridge consists of two injection-moulded items, which have been ultrasonic welded together, see figure 53.
- Each shell has three energy directors, see figure 53 (six per cartridge), which have been placed male/female alternately.
- The welding takes place by way of a specially manufactured welding horn and a fixture on a 20 kHz welding machine.
- The welding time including fixing time is approx. 1,5 second.

In the production the welding may take place fully automated inline with an injection-moulding machine.

Vertical guide-way:

- Nominal air around the stick is 0,15 mm all the way round (0,3 mm in each direction).
- The width of the guide in the edge is 1,2 mm. See figure 54.

- To make sure that the sticks can be handled smoothly without being squeezed by the cartridge and without capsizing (lateral sticks have a tendency of that), the welding has to be as precise as possible.

Cartridge, spring lock:

- To ensure that the sticks cannot be removed from the cartridge in case of shocks when handling, they are held back by a spring lock built into the item. Shown in figure 55 and 56.
- The blocking of the spring locks can only be removed, when the stick is taken out of the stick mover.

Data and specifications

- Welded in impact modified PS
  - Good mechanical properties
  - Suitable for ultrasonic welding
  - Inexpensive material, approx. DKK 8 per kilo
- Physical data, LC:
  - Volume: 2 x 21500 mm^3
  - Weight: 2 x 22,6 g
  - Main dimensions (L x W x D): 160 x 13,2 x 25 mm
- Physical data, CC:
  - Volume: 2 x 8200 mm^3
  - Weight: 2 x 8,6 g
  - Main dimensions (L x W x D): 160 x 13,2 x 25 mm

Floating cartridge Bottom

Function

To ensure that the sticks in the cartridge are always in the top of the cartridge, and that the stack of sticks is kept in place, the bottoms shown in figure 57 have been used.

Applied solution

The item has been made of bent sheet metal, so that its shoulders are flexible and act as a lock. The lock runs against four internal one-way stairs in the cartridge (see illustration in figure 57 and 58).
Items for function models have been made of stainless steel by way of laser cutting and bending.

When the cartridge has been emptied for sticks, and the bottom is in the top of the cartridge, a 45-degree bend ensures that the stick mover pawl will slide over the bottom. The bottom is guided between the four legs and the side-guidance of the stairs shown in figure 58.

Data and specifications

0,10 mm stainless spring steel, AISI 301

Laser cutting/photo etching items for function models

Bended in specially manufactured tools

Loading sticks in cartridge

The sticks are mounted in the cartridge in the following way, see figure 59 for illustration:

A bottom is placed in a temporary fixture.

- 50 lateral or 100 colorimetric sticks are placed in the fixture. The recesses in the end of the stick guide the sticks, see figures 49 and 50.
- The cartridge is taken down to the fixture. The bottom gets in contact with the one-way stairs in the shells.

To get the sticks to the top of the cartridge, the cartridge is held, while the auxiliary plate of the fixture is being pushed upwards.

To secure that the stack of sticks are kept in place, cartridges may be loaded and unloaded in a keeper.

CLAIMS

1. An apparatus for analysing fluid taken from a body, said apparatus comprising
- at least one storage storing sticks and/or other kinds of biosensors to which the fluid is to be dosed;
- at least one incubator being distinct from the storage;
and
- transfer means for transferring sticks from the storage to the incubator.

2. An apparatus according to claim 1, wherein the incubator comprises first fluid dosing means for dosing the body fluid to be analysed to a stick.

3. An apparatus according to claim 1 or 2, wherein the apparatus comprising second dosing means for dosing other fluids to the sticks and/or biosensors.

4. An apparatus according to any of the preceding claims wherein the incubator further comprises thermostation means for heating and cooling.

5. An apparatus according to any of the preceding claims wherein the storage further comprises thermostation means for heating and cooling.

6. An apparatus according to any of the preceding claims wherein the incubator further comprises reading means for detection of a signal produced on a stick or biosensor after application of the fluid.

7. An apparatus according to any of the preceding claims wherein the incubator further comprises stick removal means.

8. An apparatus according to any of the preceding claims wherein the incubator further comprises an incubator disc comprising means for positioning, keeping and guiding sticks during the incubation.

9. An apparatus according to any of the preceding claims wherein the storage comprises a storage disc.

10. An apparatus according to any of the preceding claims further comprising means for rotation of the incubator disc.

11. An apparatus according to claim 9 further comprising means for rotation of the storage disc.

12. An apparatus according to any of the preceding claims further comprising means for monitoring the number of used sticks.

13. An apparatus according to any of the preceding claims further comprising means for conditioning humidity content in the storage.

14. An apparatus according to any of the preceding claims further comprising means for conditioning ammonia content in the storage.

15. An apparatus according to any of the preceding claims comprising computer means.

16. An apparatus according to any of the preceding claims further comprising a user interface comprising at least one of the following;

- a keyboard
- a screen
- a cartridge loading station
- a stickwaste container loading station
- a diluent container loading station
- a liquid waste funnel cleaning station
- a wet system filter changing station

17. An apparatus according to any of the preceding claims further comprising variable rotating means for controlling the rotation speed of the storage disc.

18. An apparatus according to any of the preceding claims further comprising variable rotating means for controlling the rotation speed of the incubator disc.

19. An apparatus according to any of the preceding claims, wherein the storage and the incubator are thermally isolated from each other and/or isolated so as to avoid or limit humidity exchange between the storage and the incubator.

20. A method for analysing of fluid, which utilises an apparatus according to any of the preceding claims, wherein at least one rotation of the incubator disc comprises the steps of:

- loading sticks
- dosage of fluid on to the sticks
- incubation
- reading
- removal of sticks.

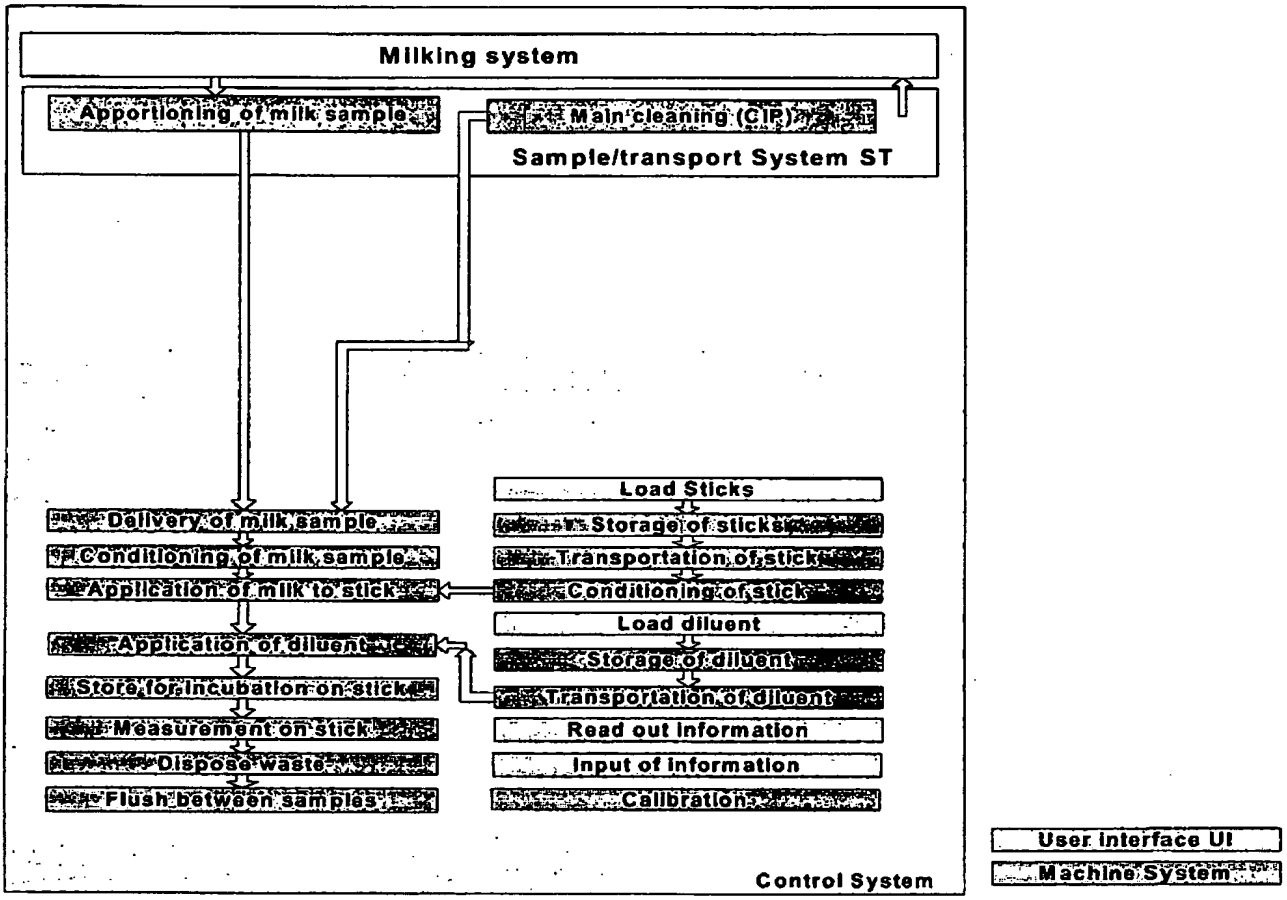


Fig. 1

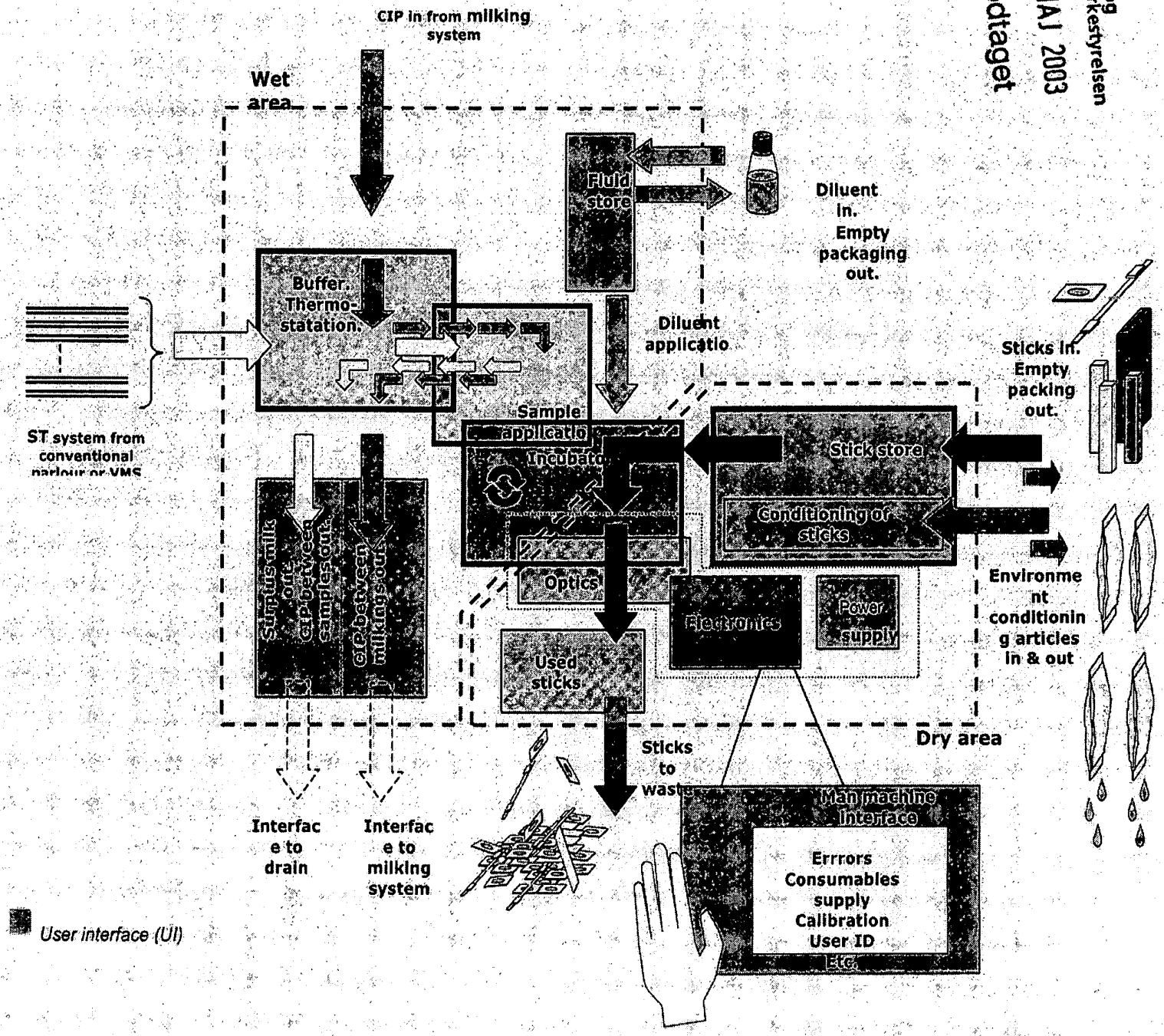


Fig. 2

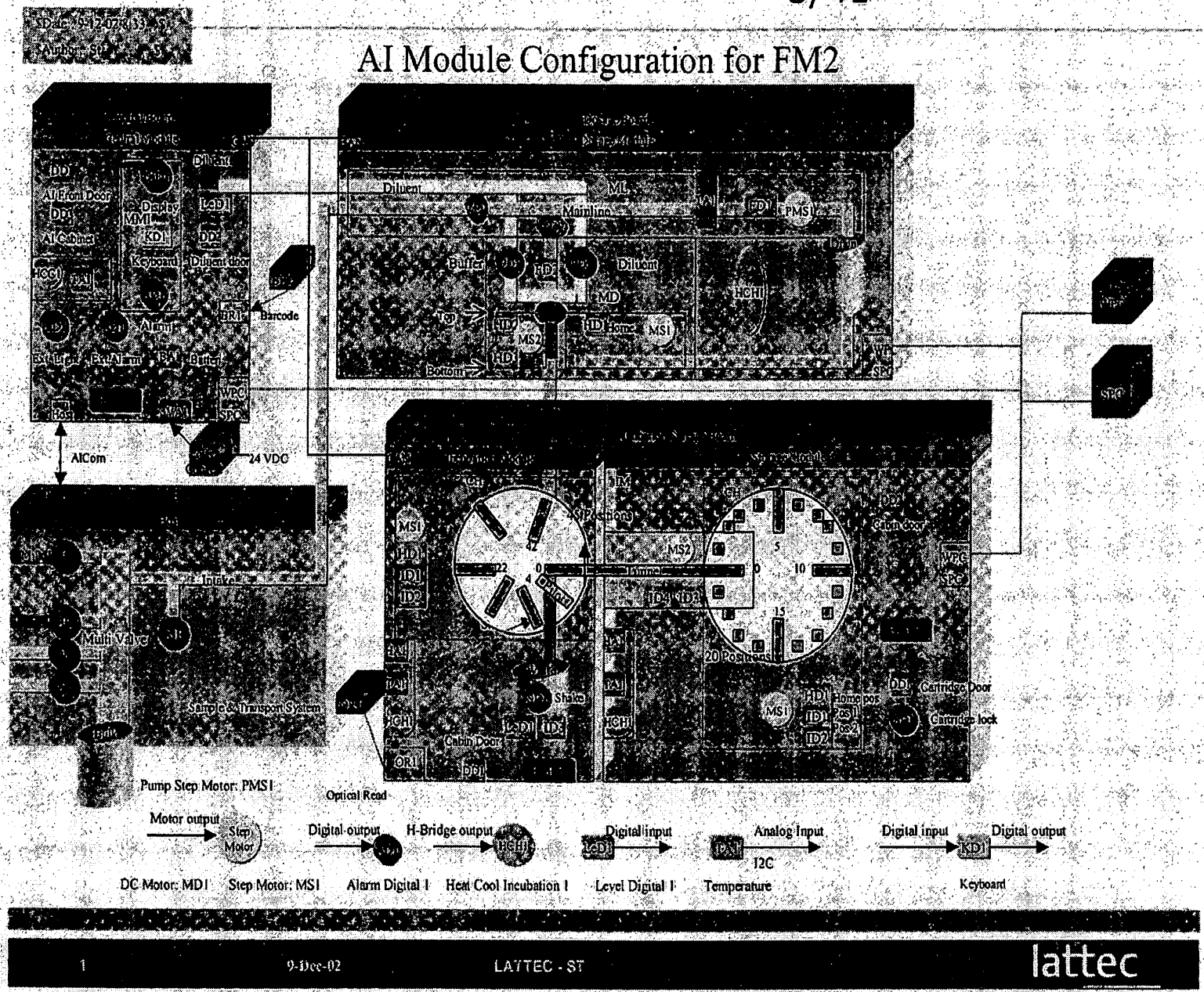


Fig. 3

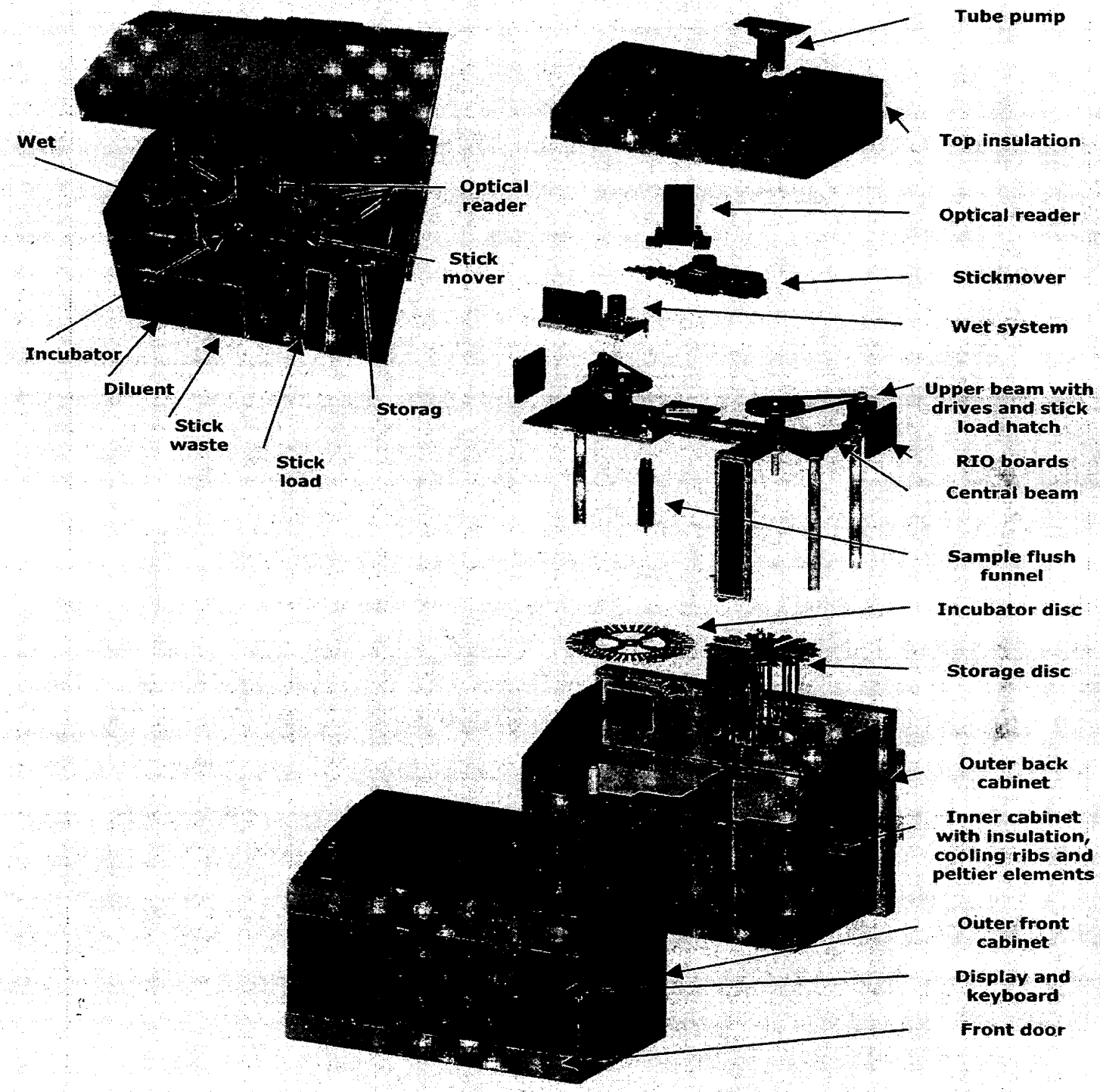


Fig. 4

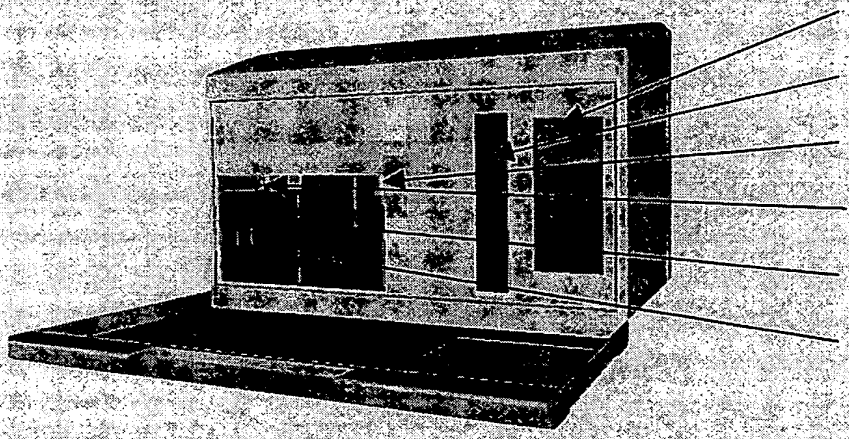


Fig. 5

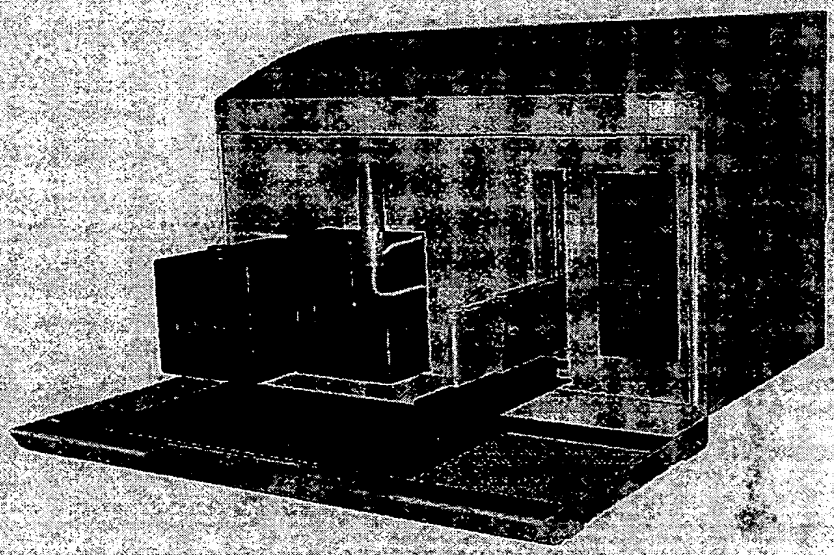


Fig. 6

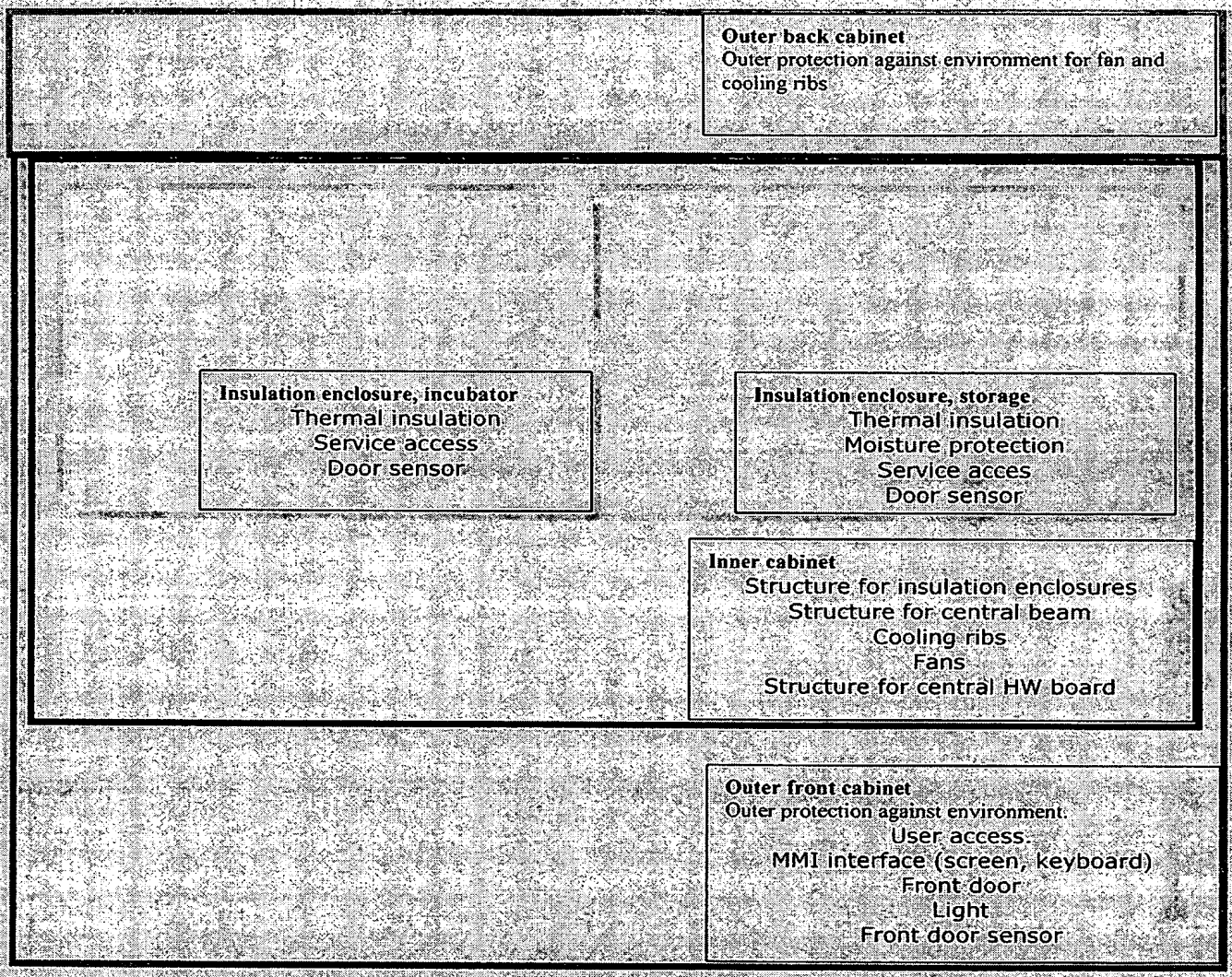


Fig. 7

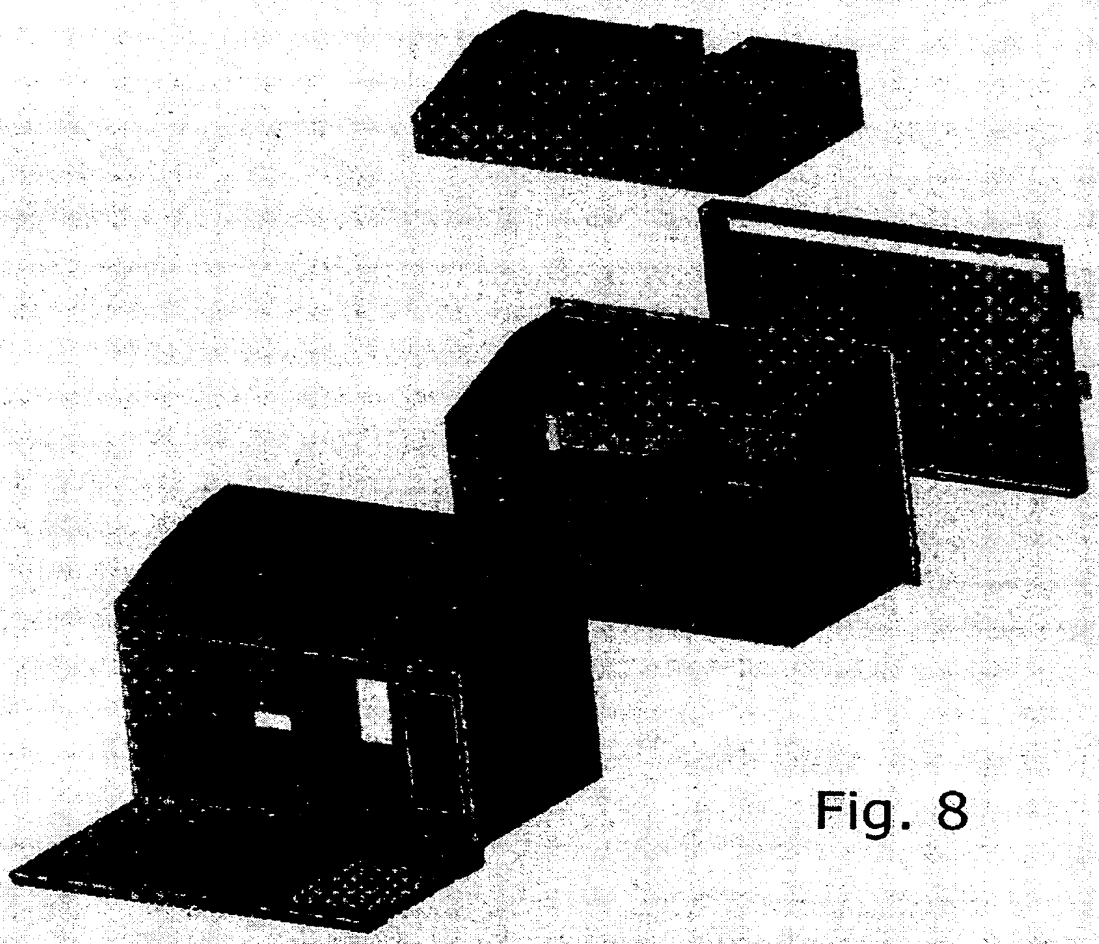


Fig. 8

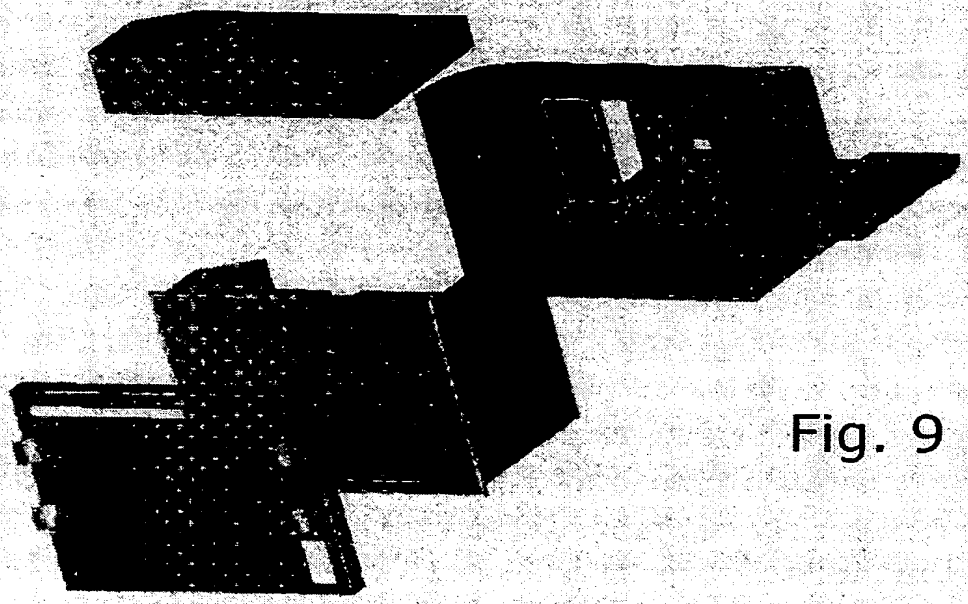
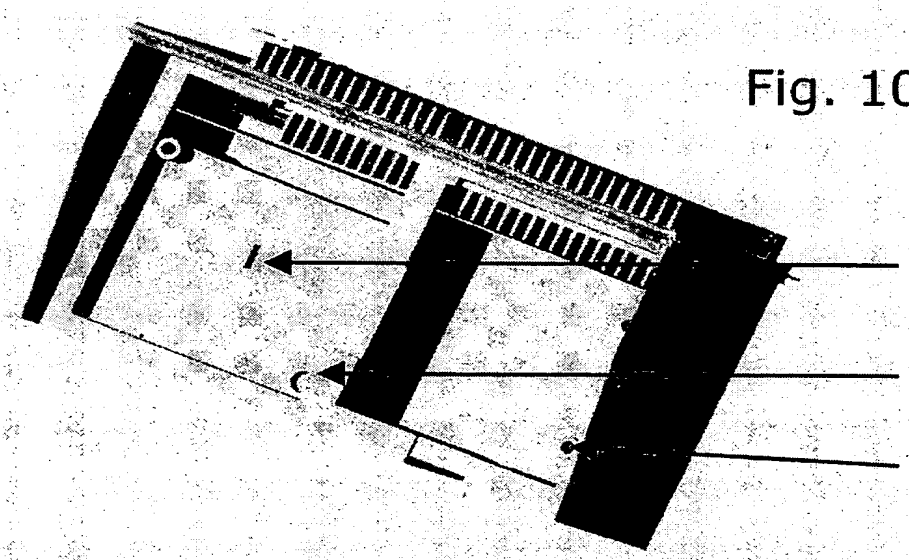


Fig. 9

Fig. 10



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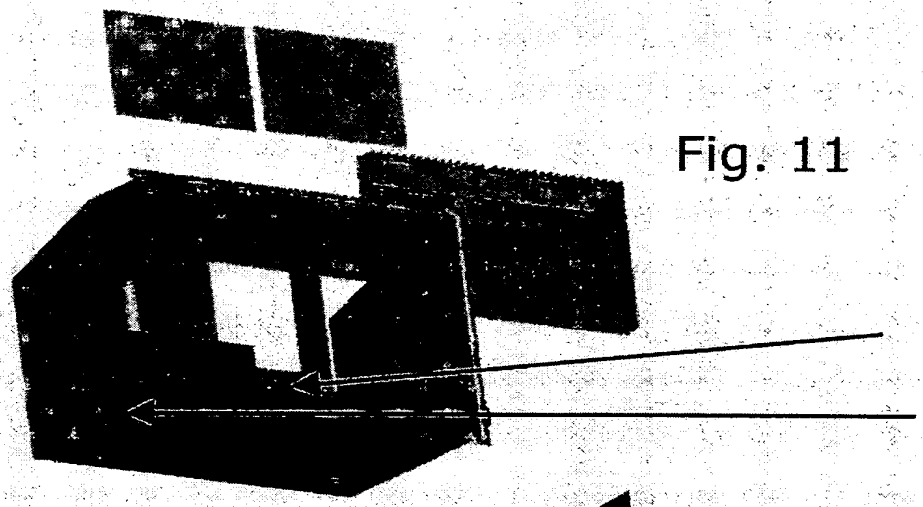


Fig. 12

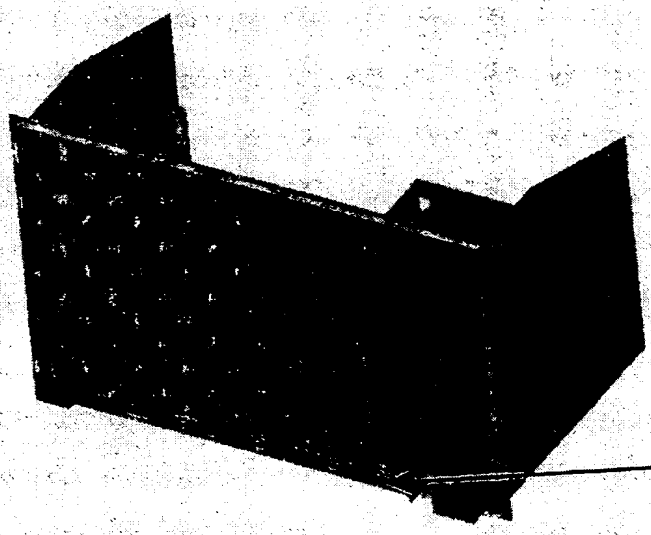
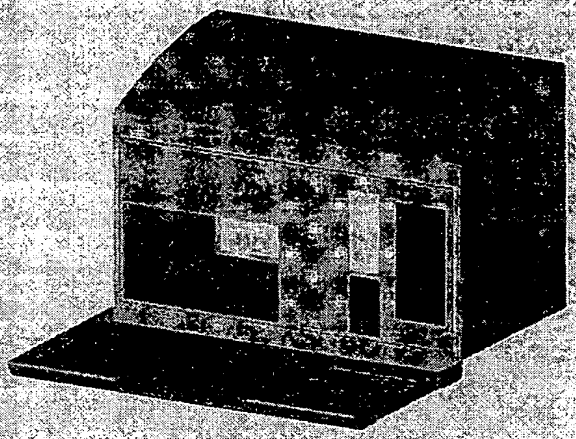
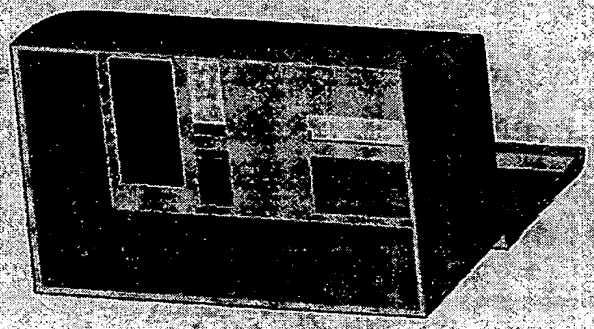


Fig. 13





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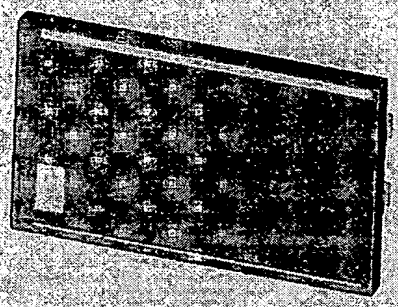

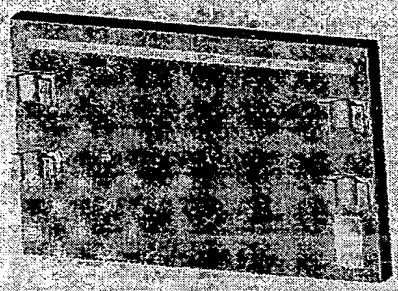

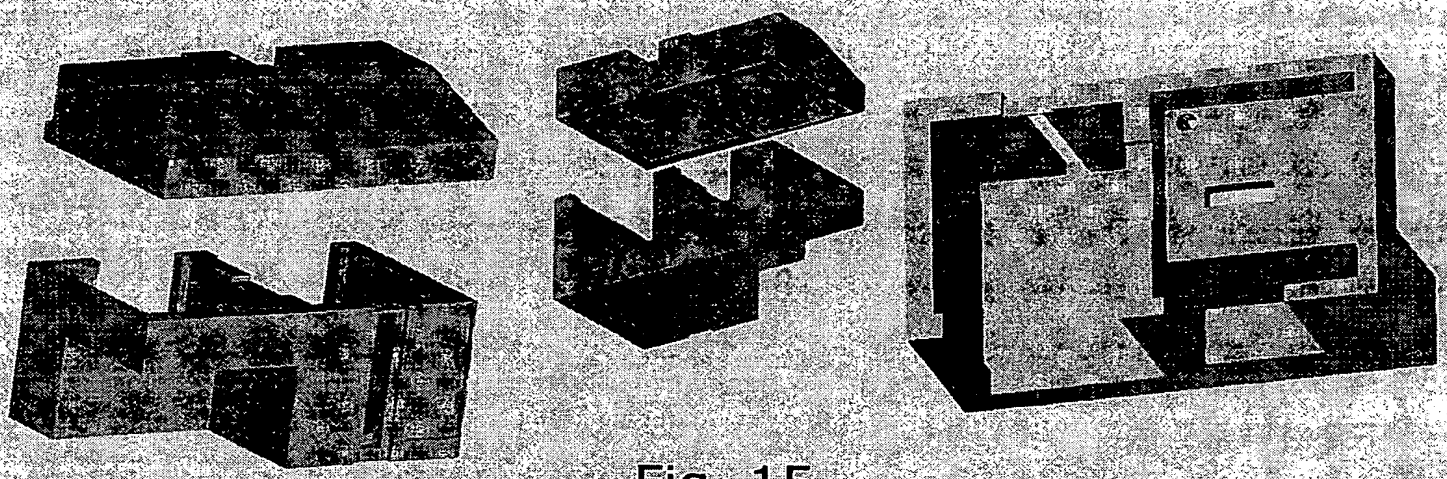

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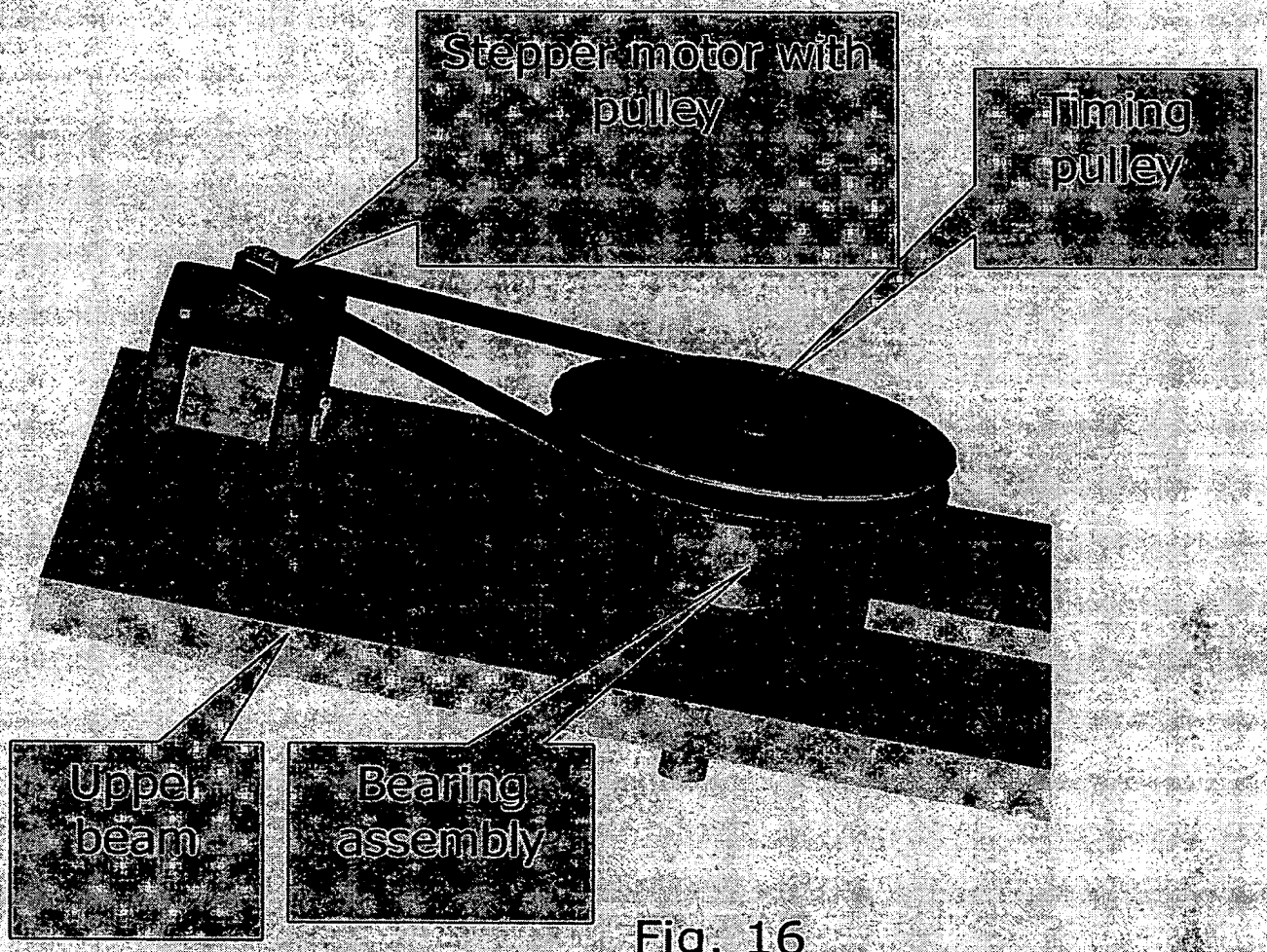


Fig. 16

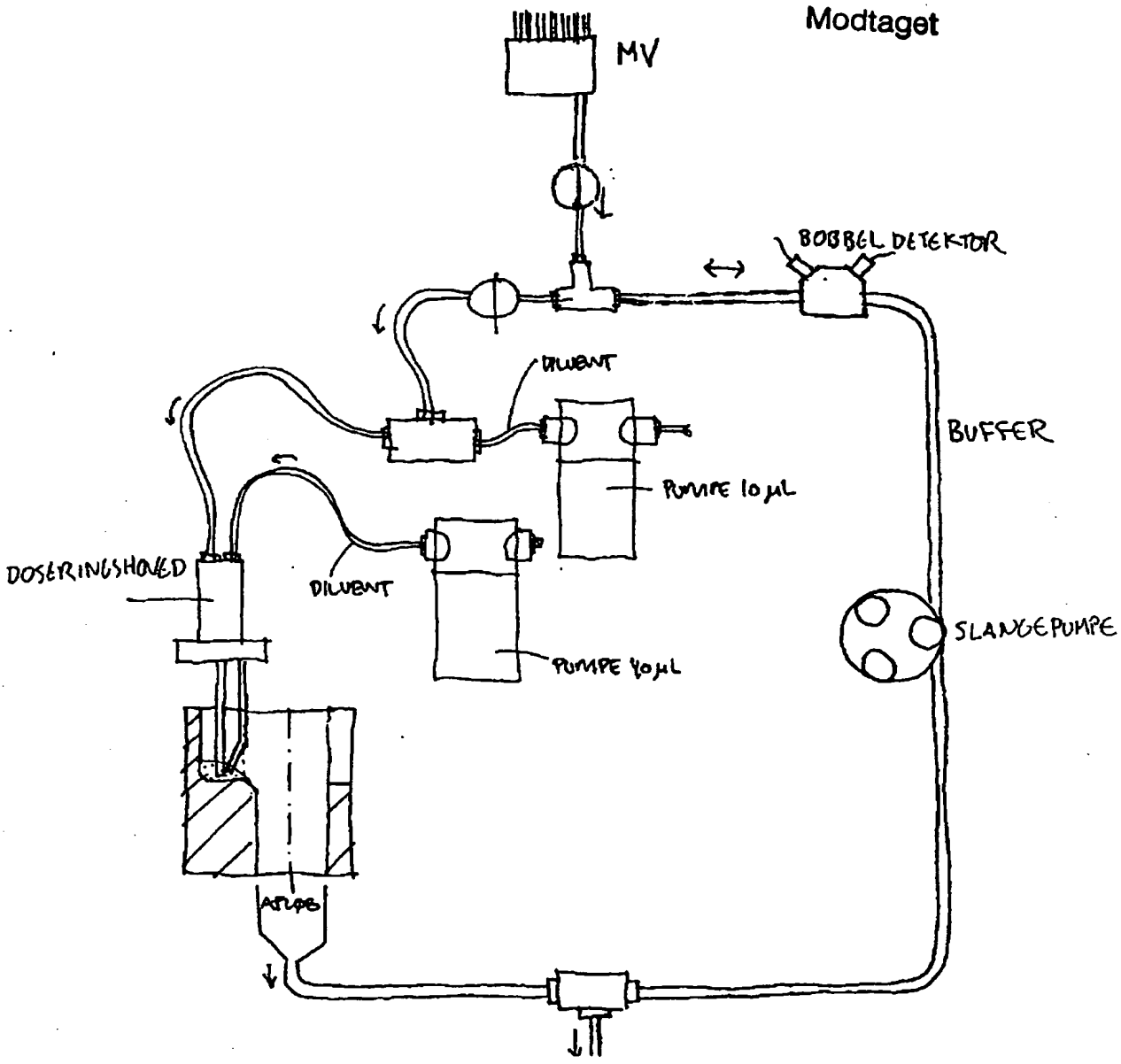


Fig. 17

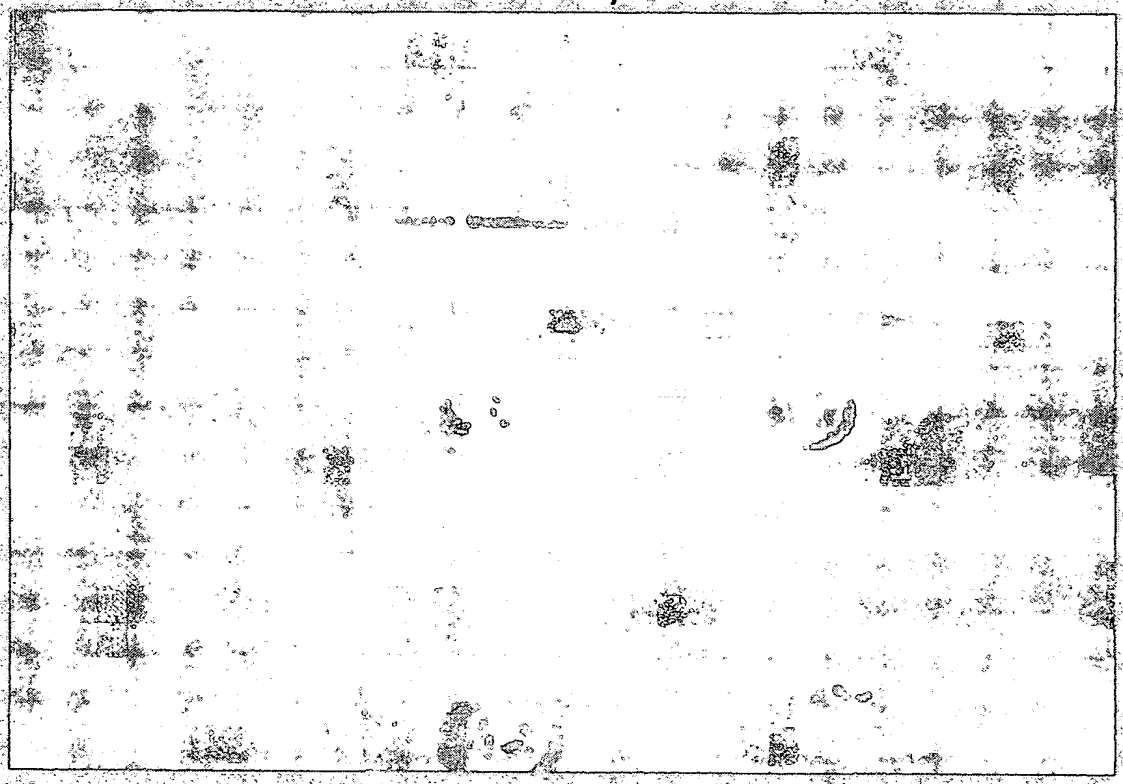


Fig. 18

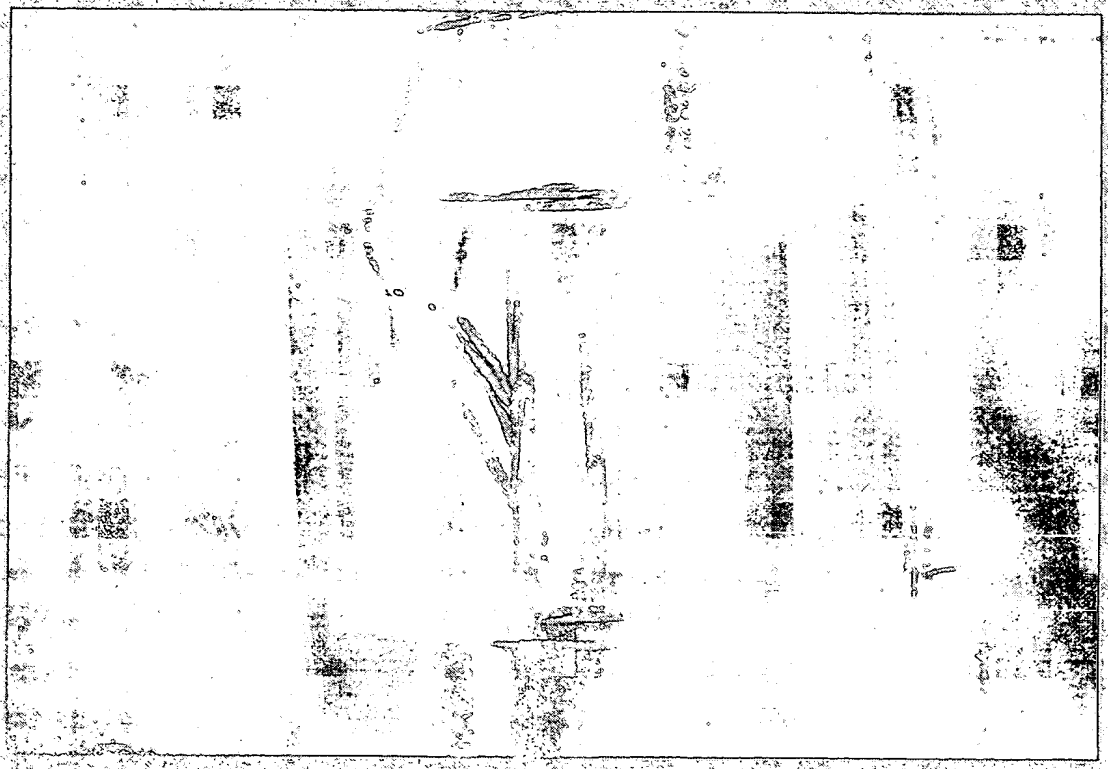


Fig. 19

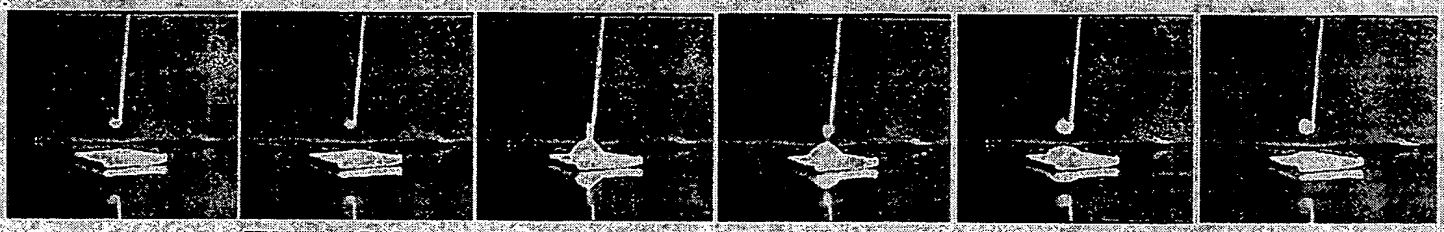


Fig. 20

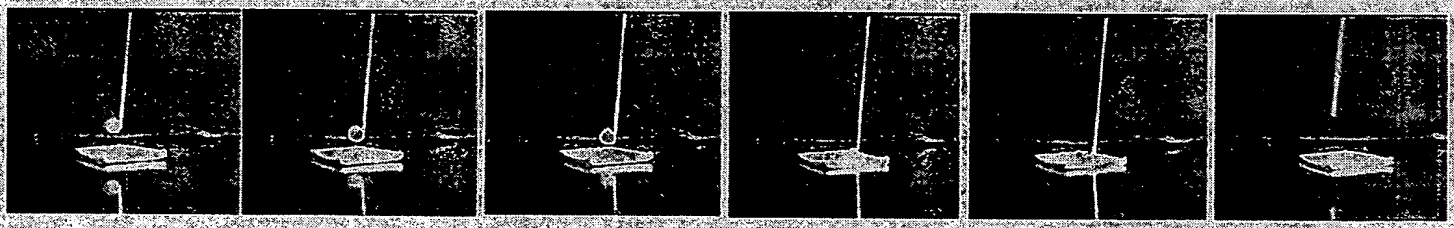
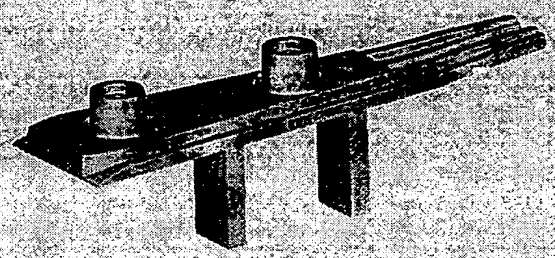


Fig. 21



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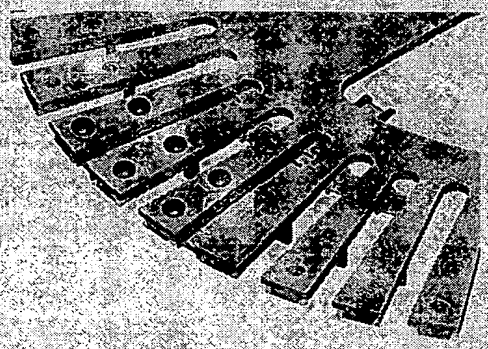


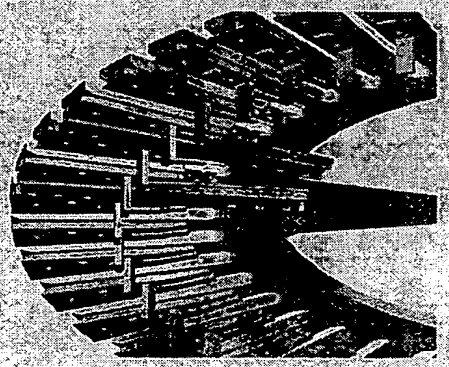
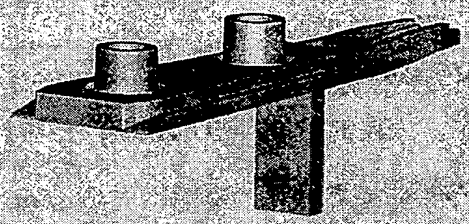
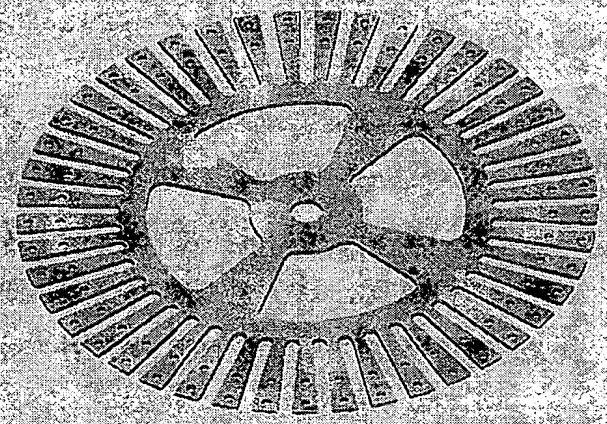


Fig. 23





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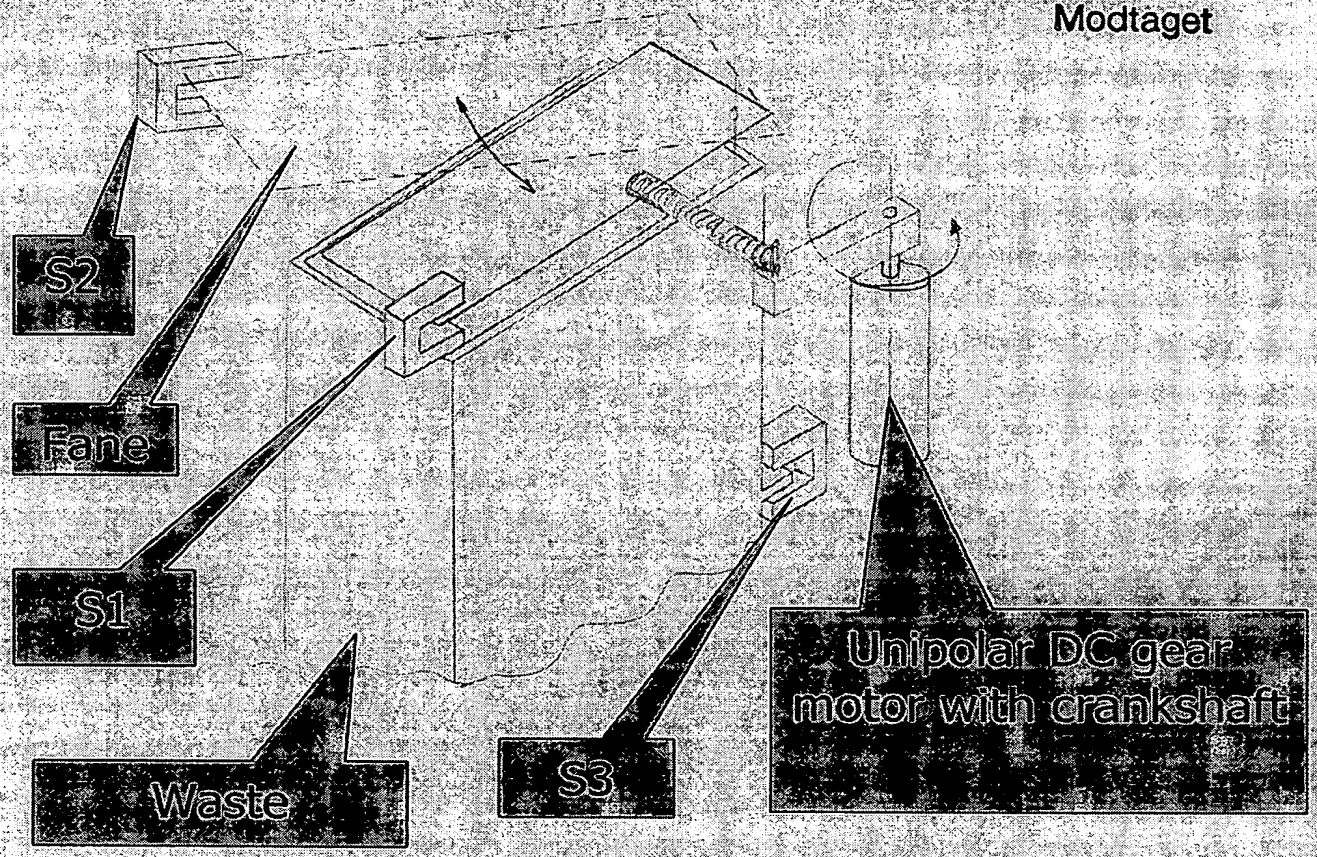


Fig. 25

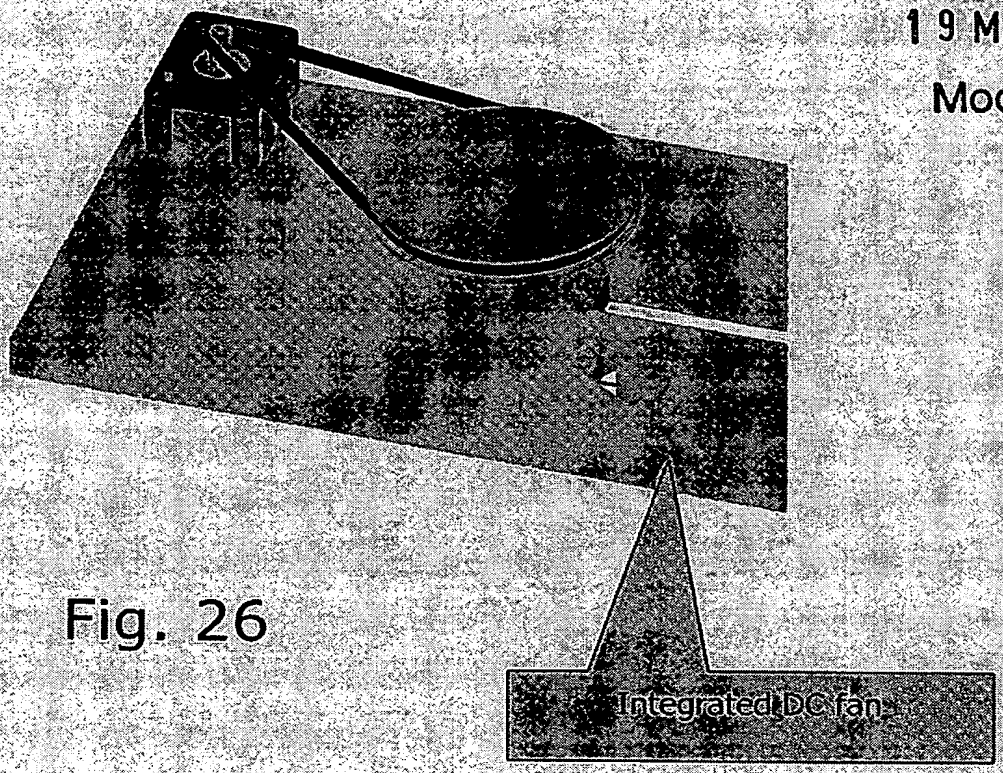


Fig. 26

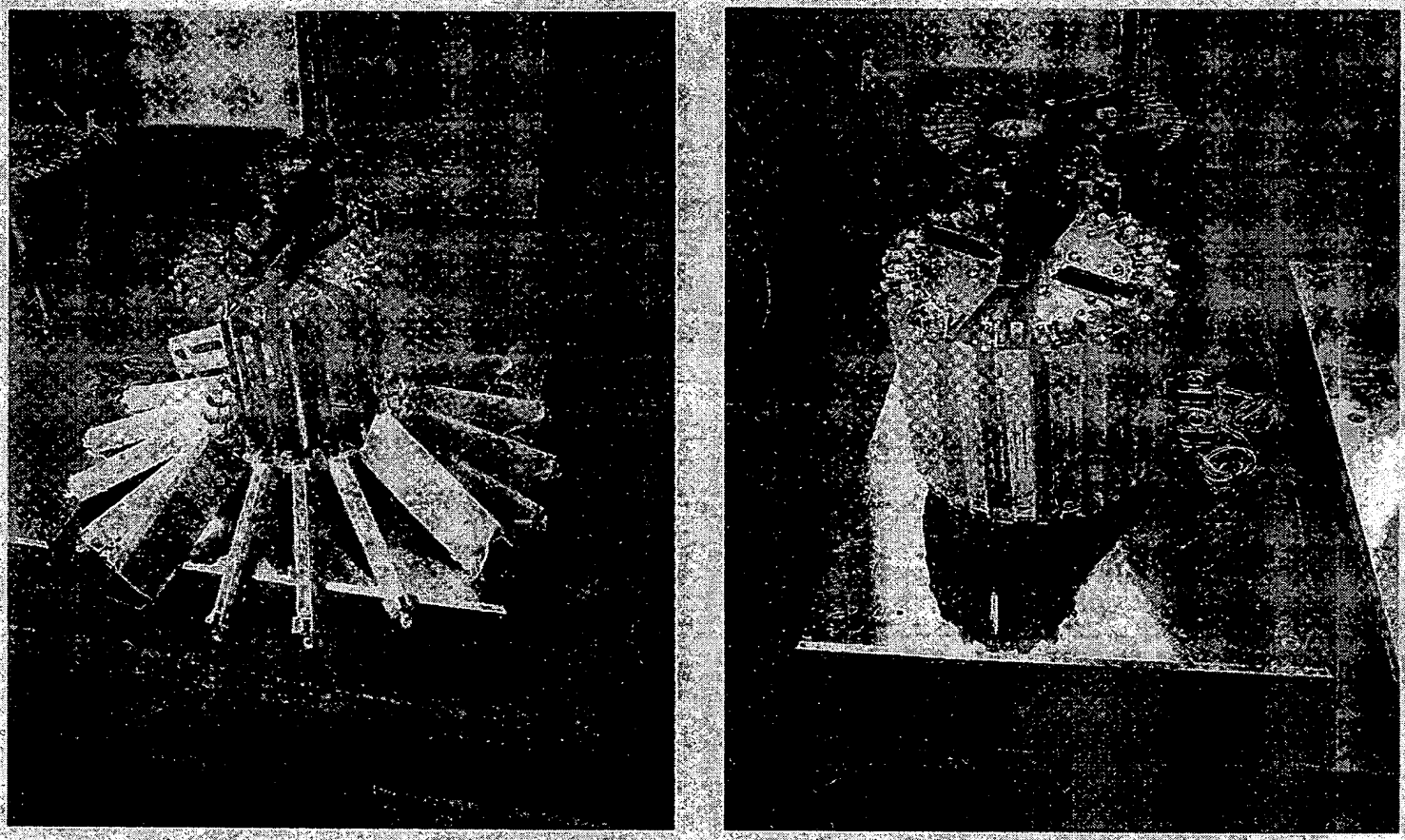


Fig. 27

Fig. 28

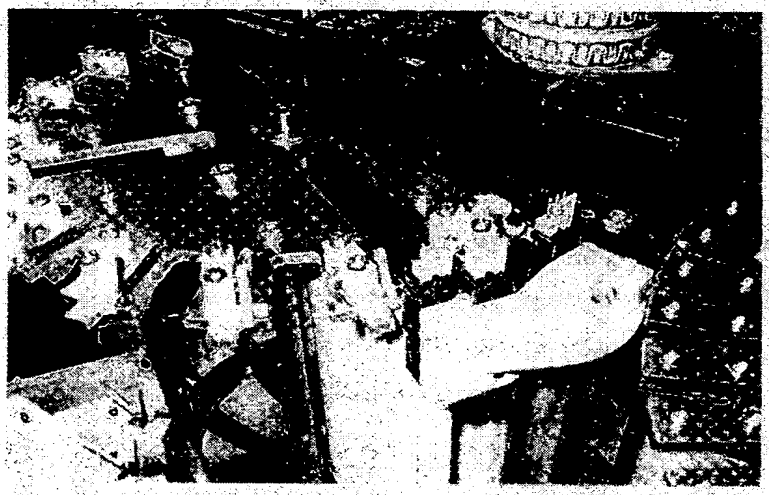


Fig. 29

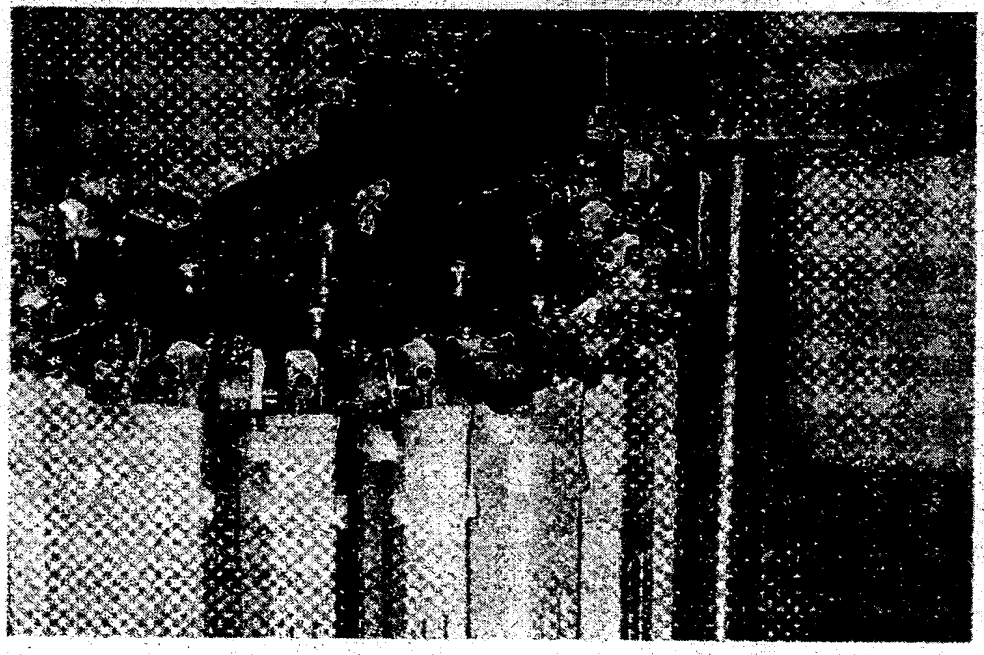
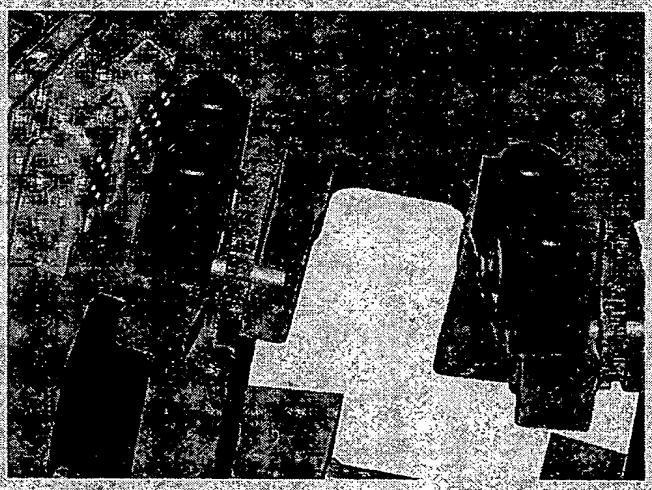


Fig. 30



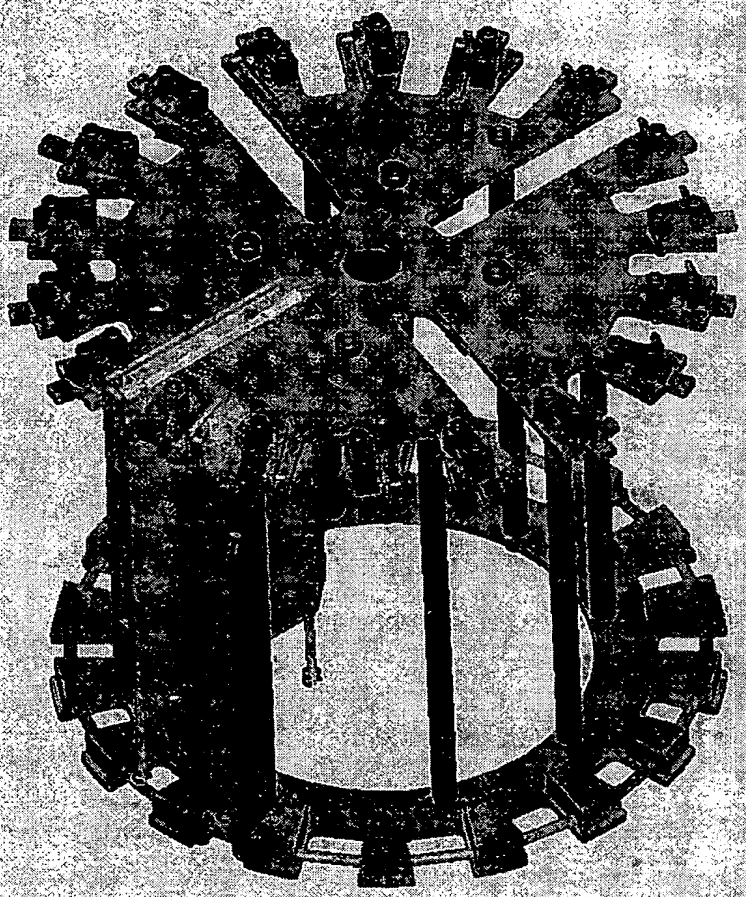
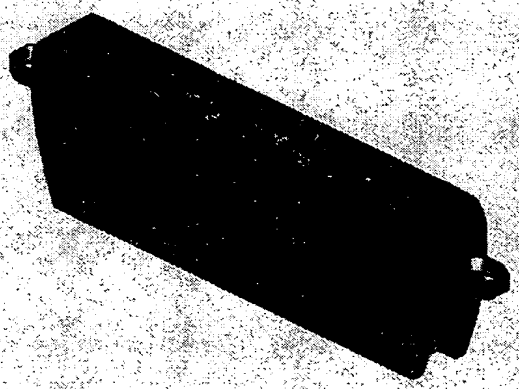
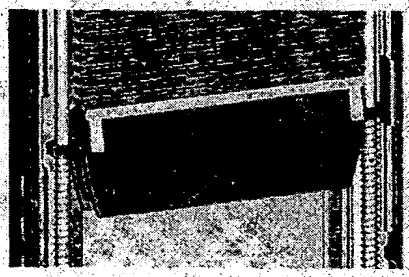
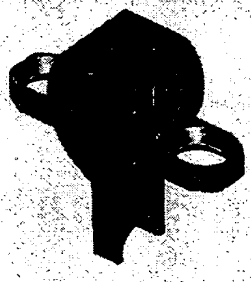


Fig. 31







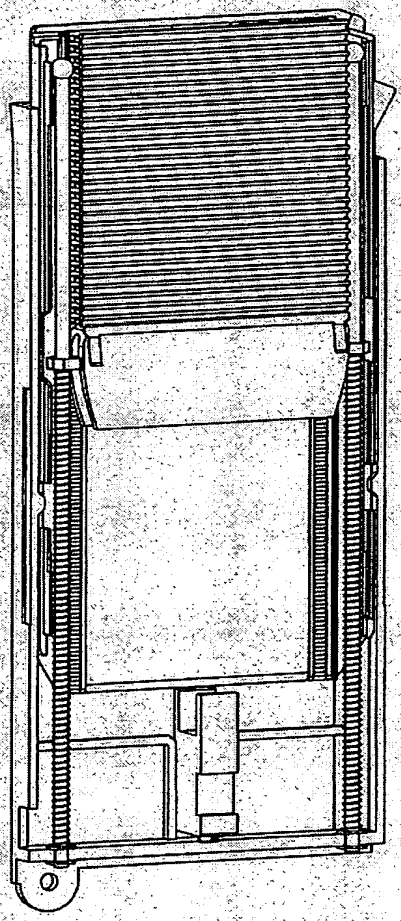


Fig. 32

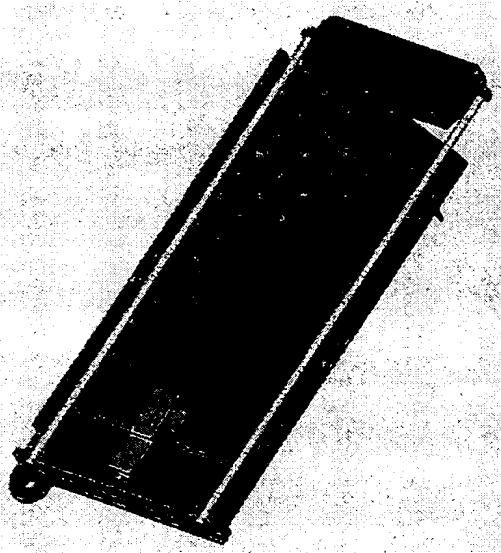


Fig. 33

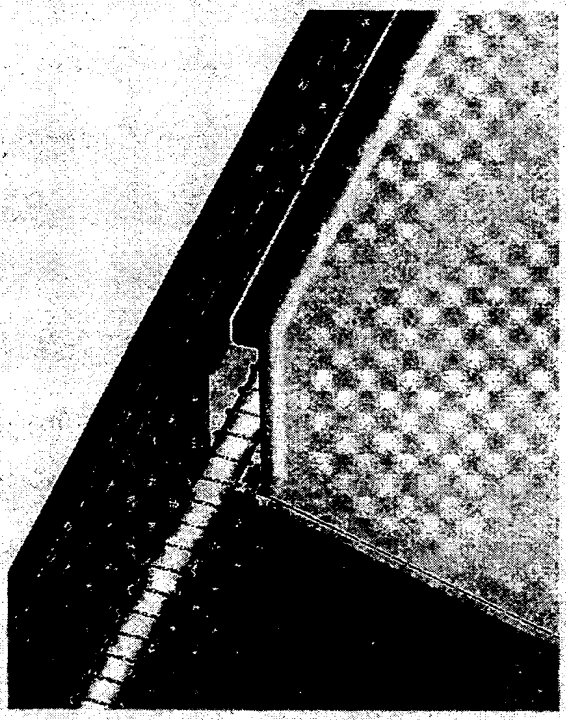


Fig. 35

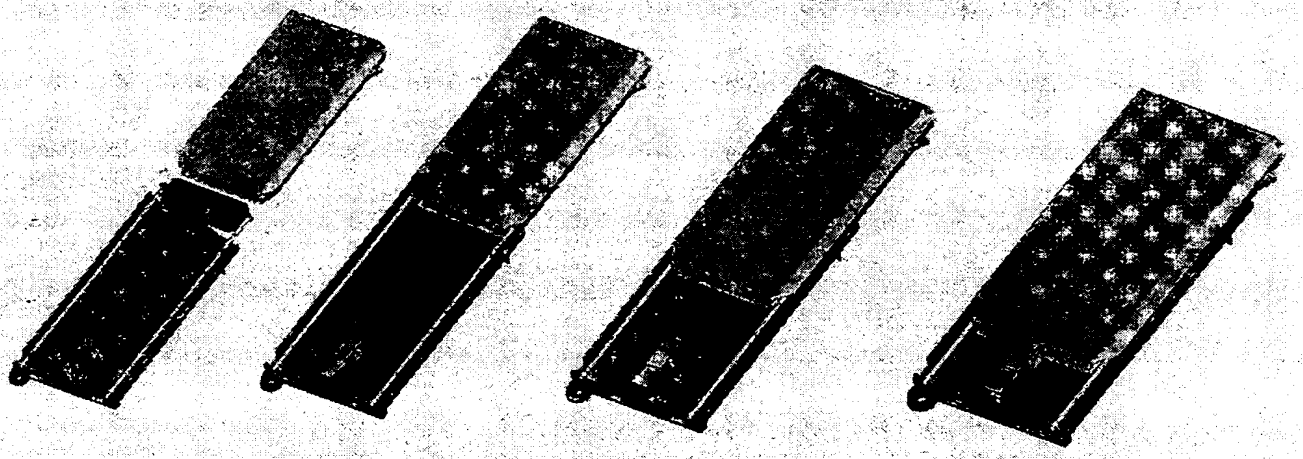
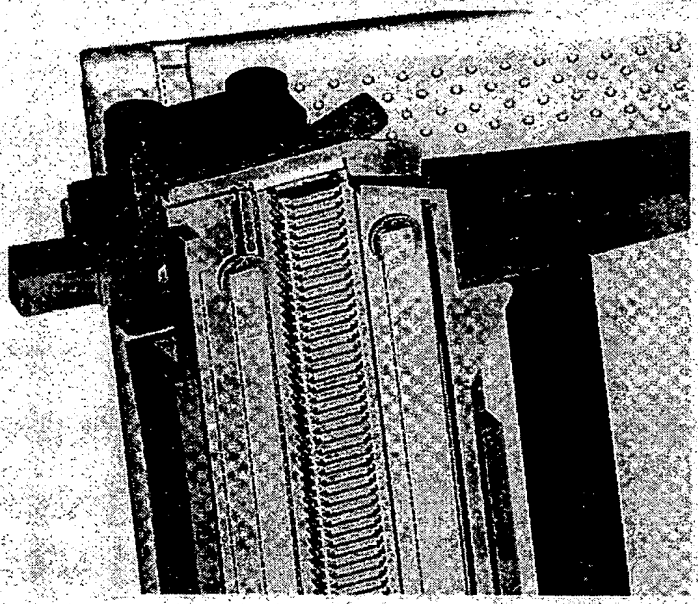


Fig. 34



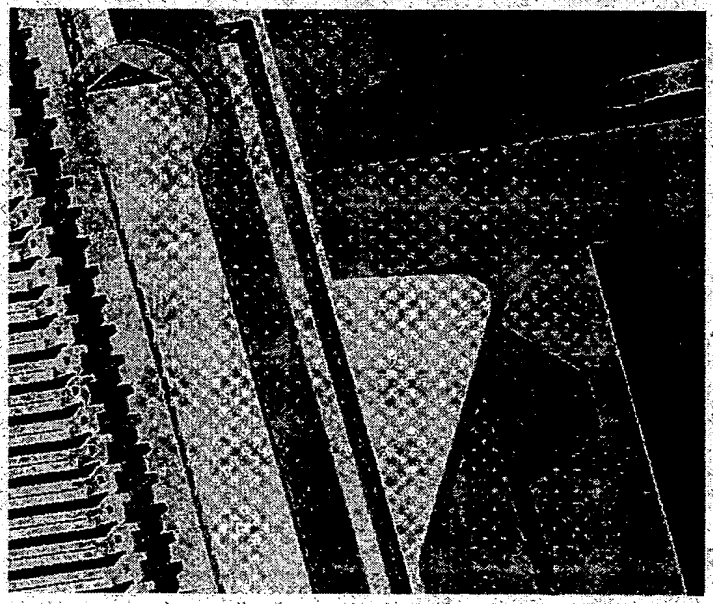


Fig. 36

Fig. 37

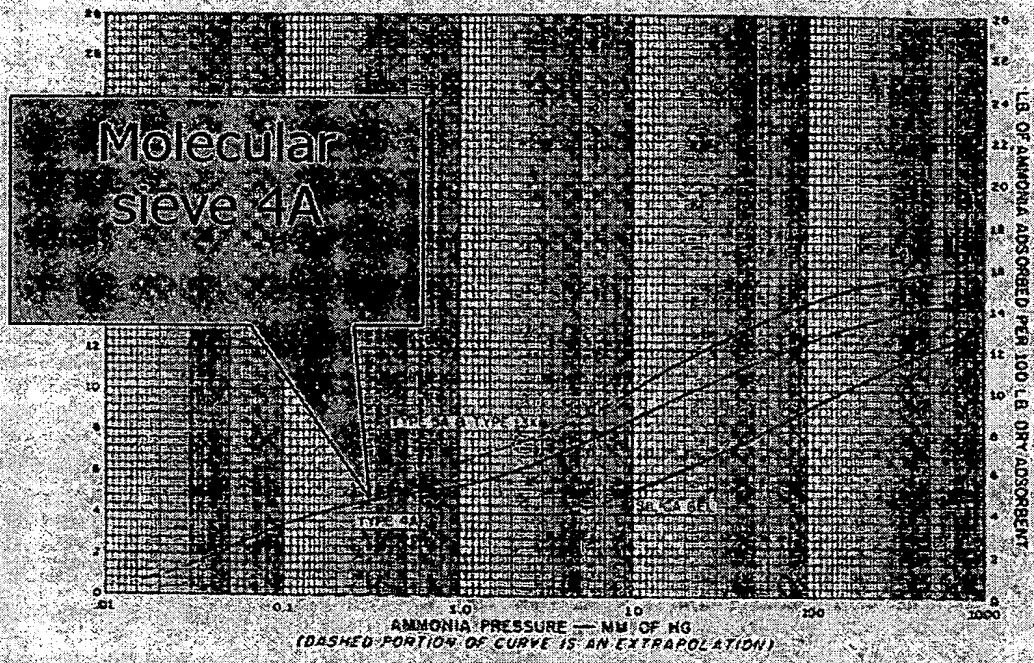
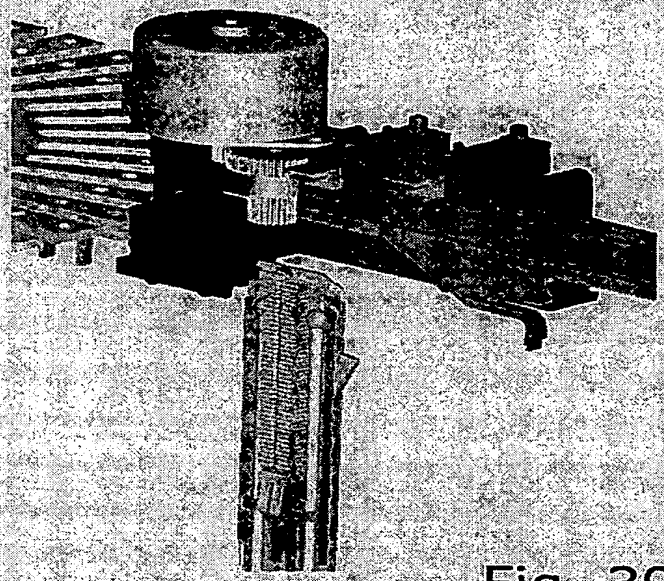


Fig. 38



Note that half of the stick-mover housing and the cartridge is removed.

Fig. 39

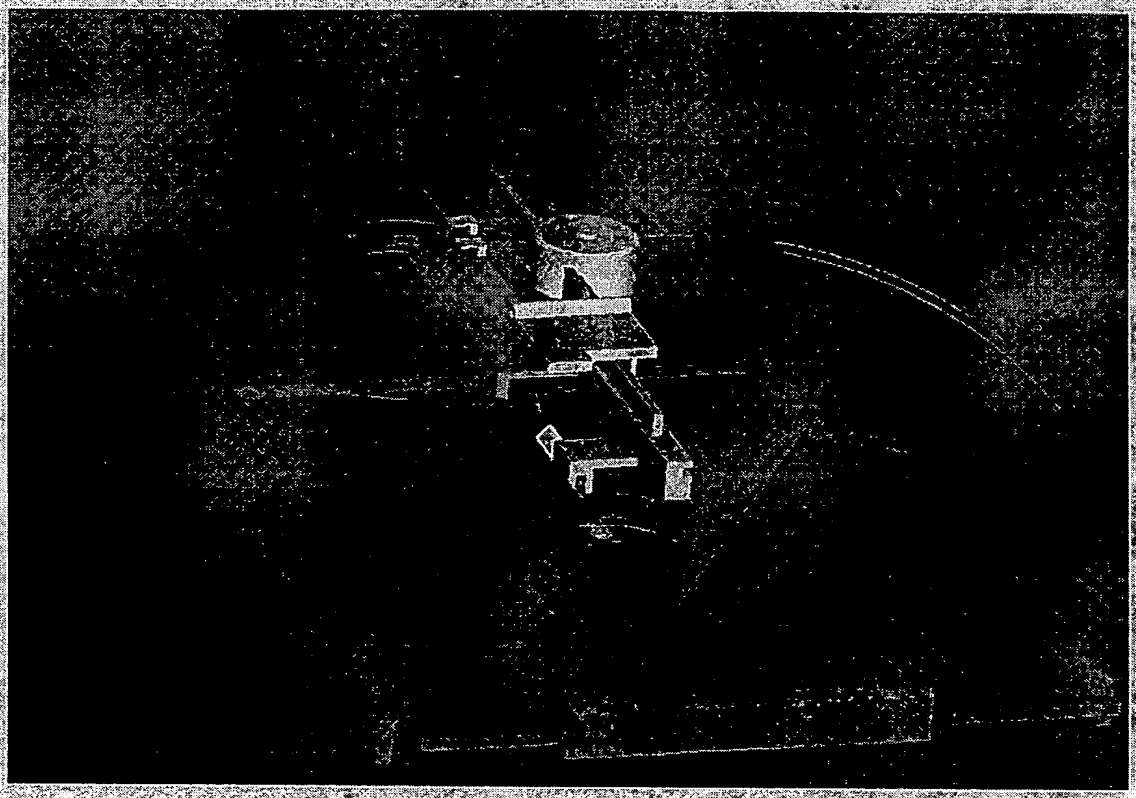


Fig. 40

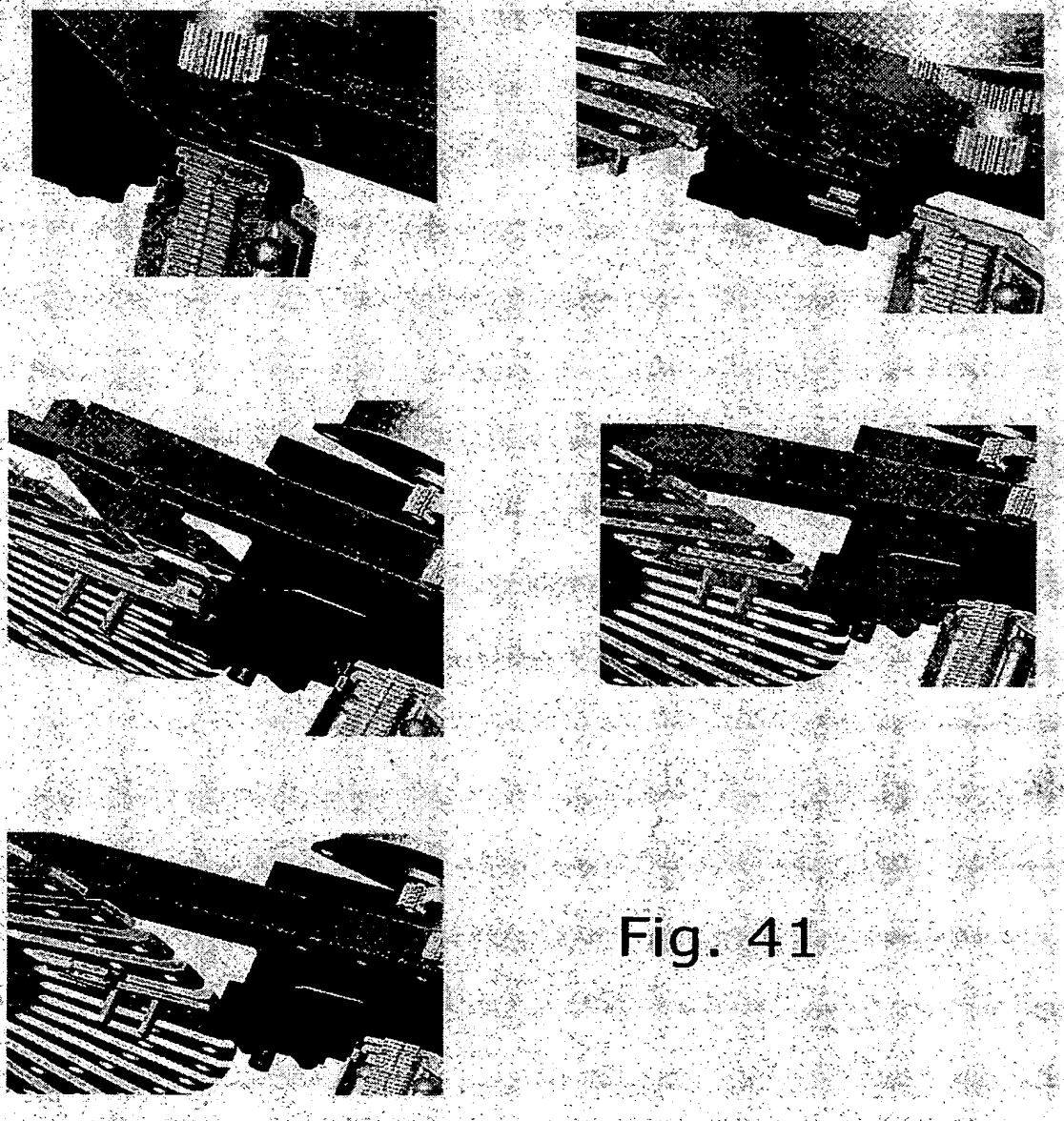


Fig. 41

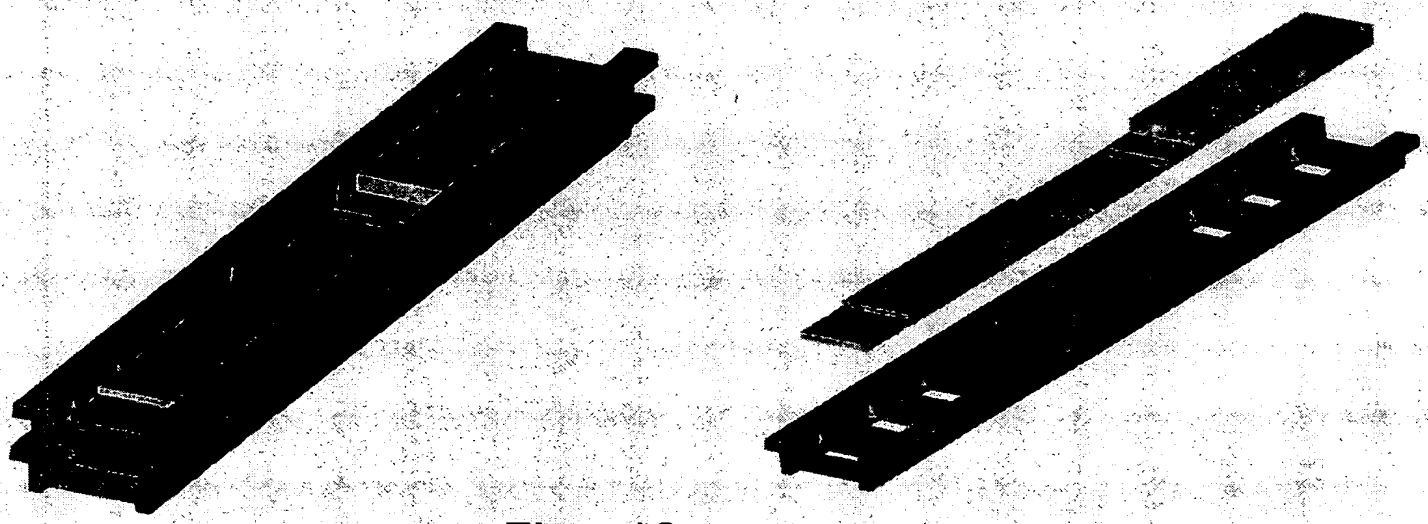


Fig. 42

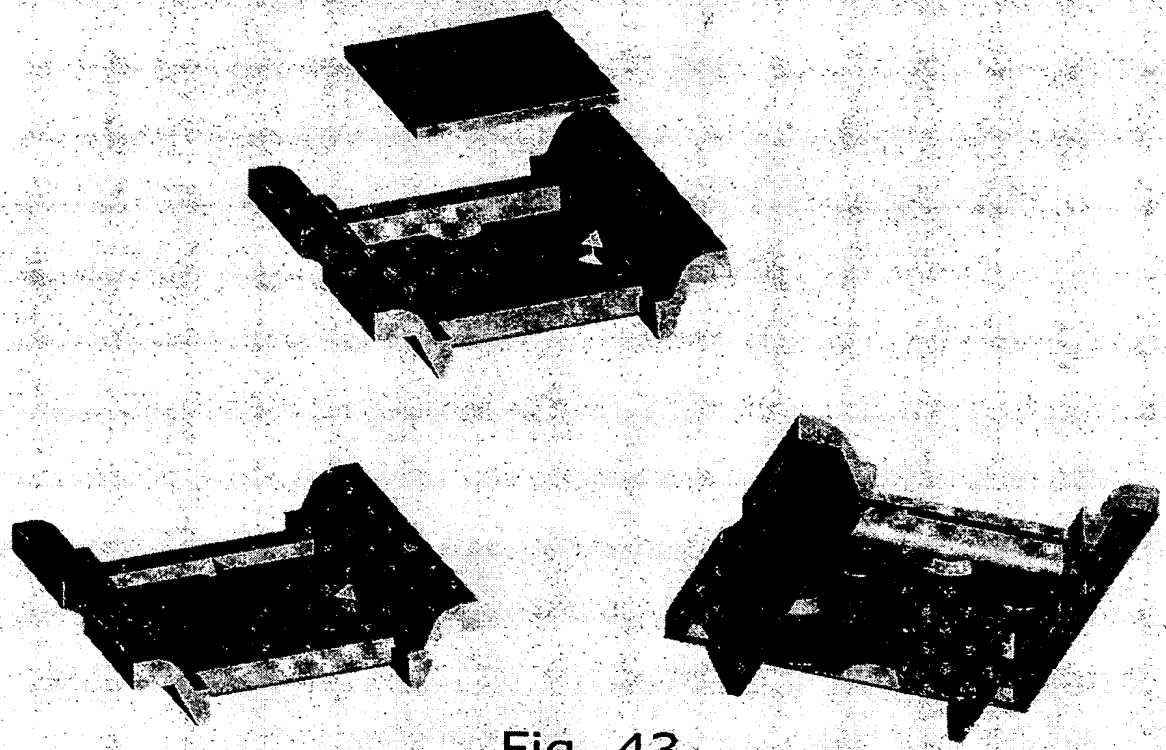
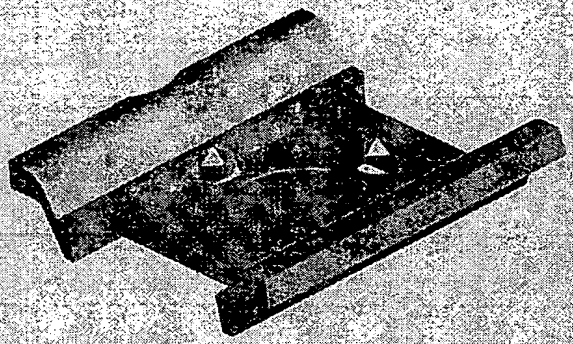


Fig. 43



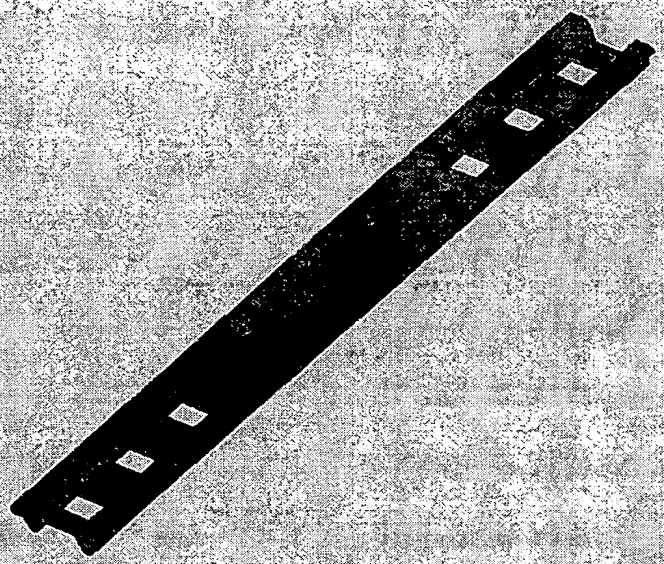


Fig. 44

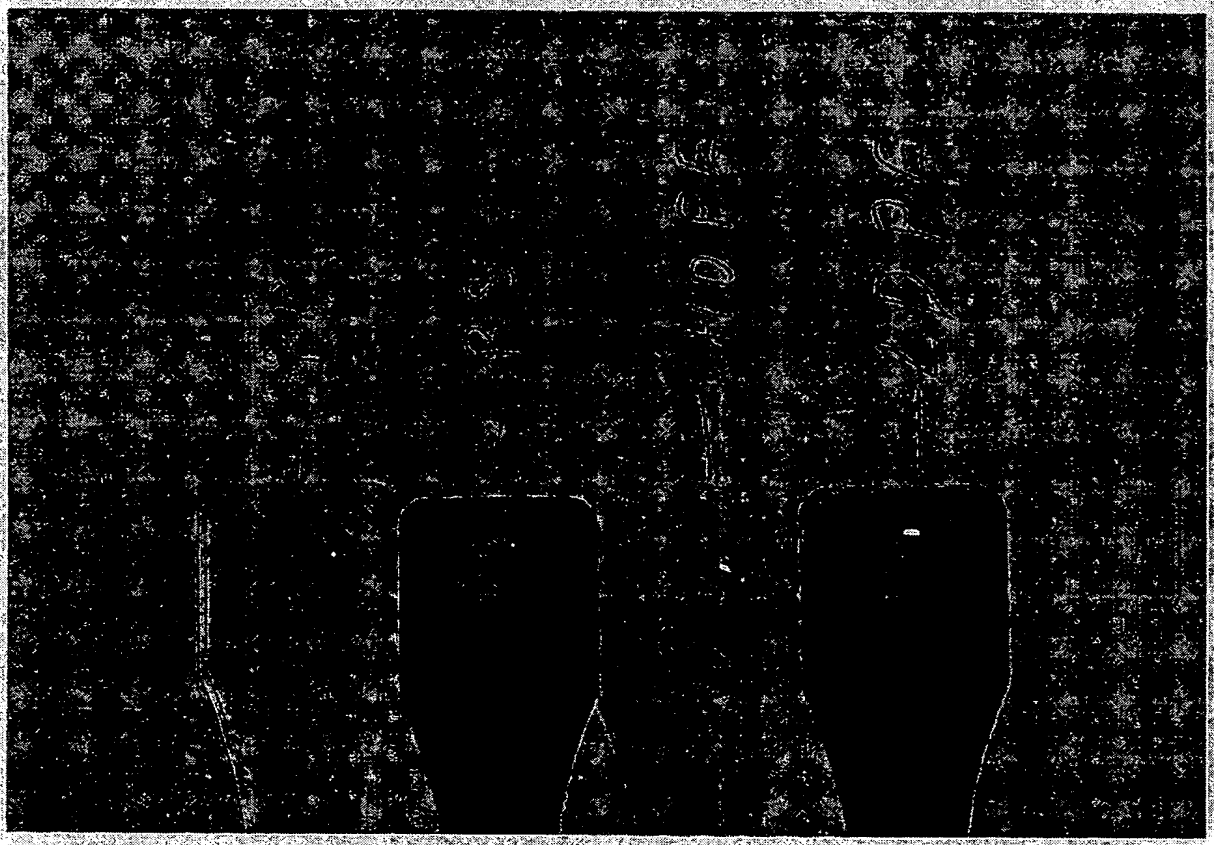


Fig. 45

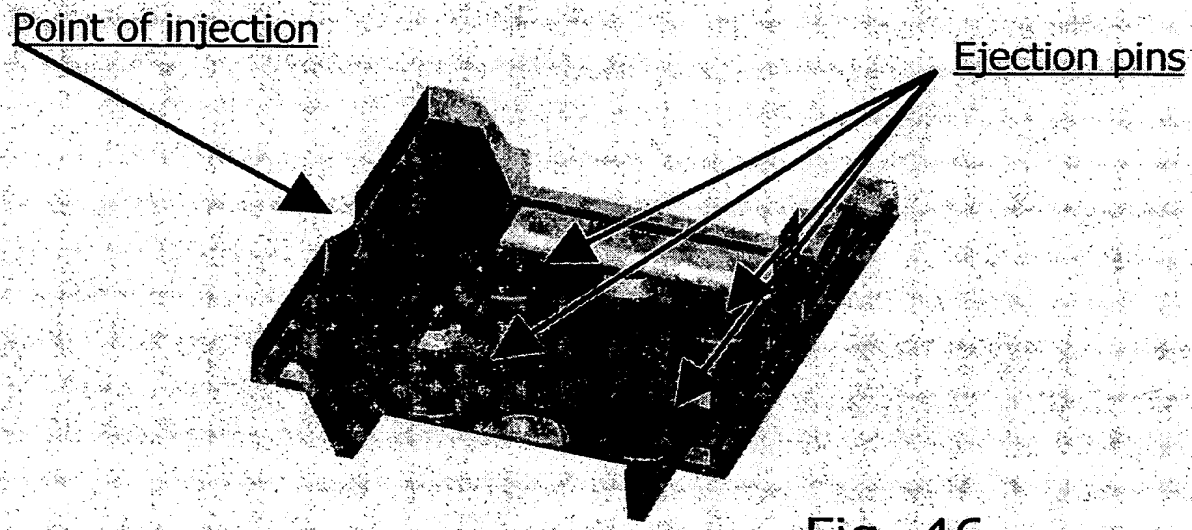


Fig. 46

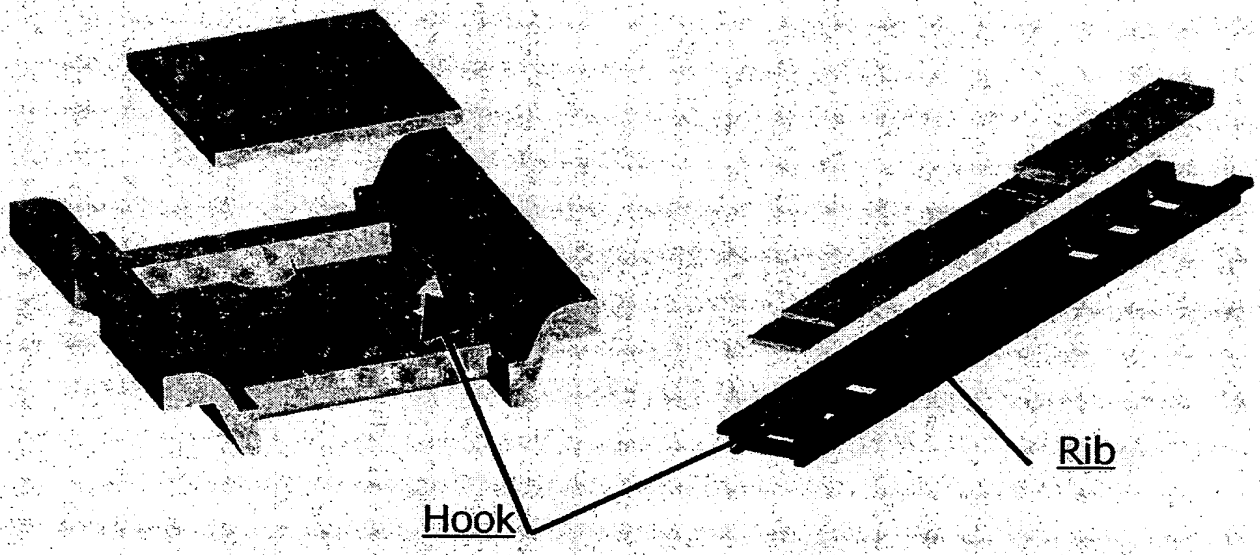


Fig. 47

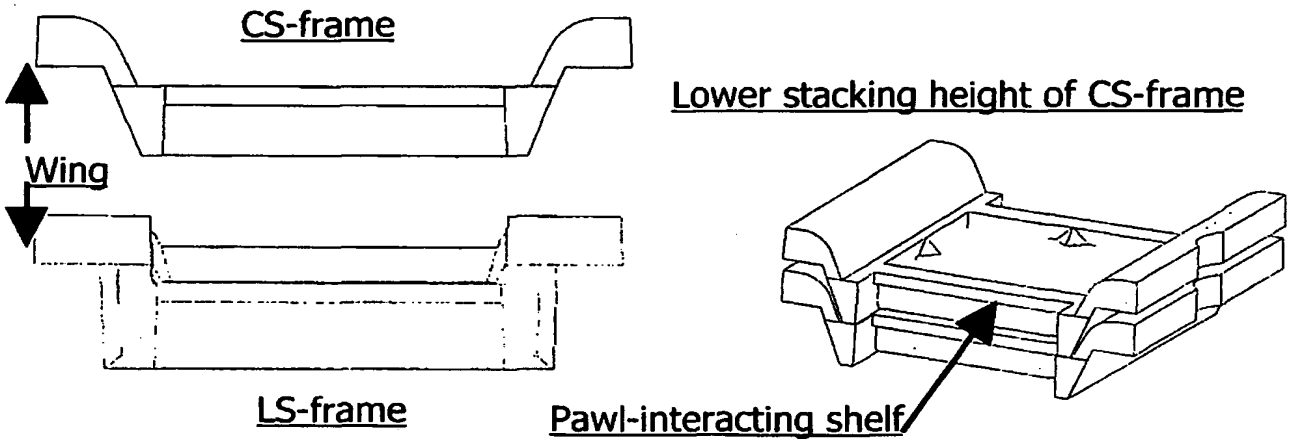


Fig. 48

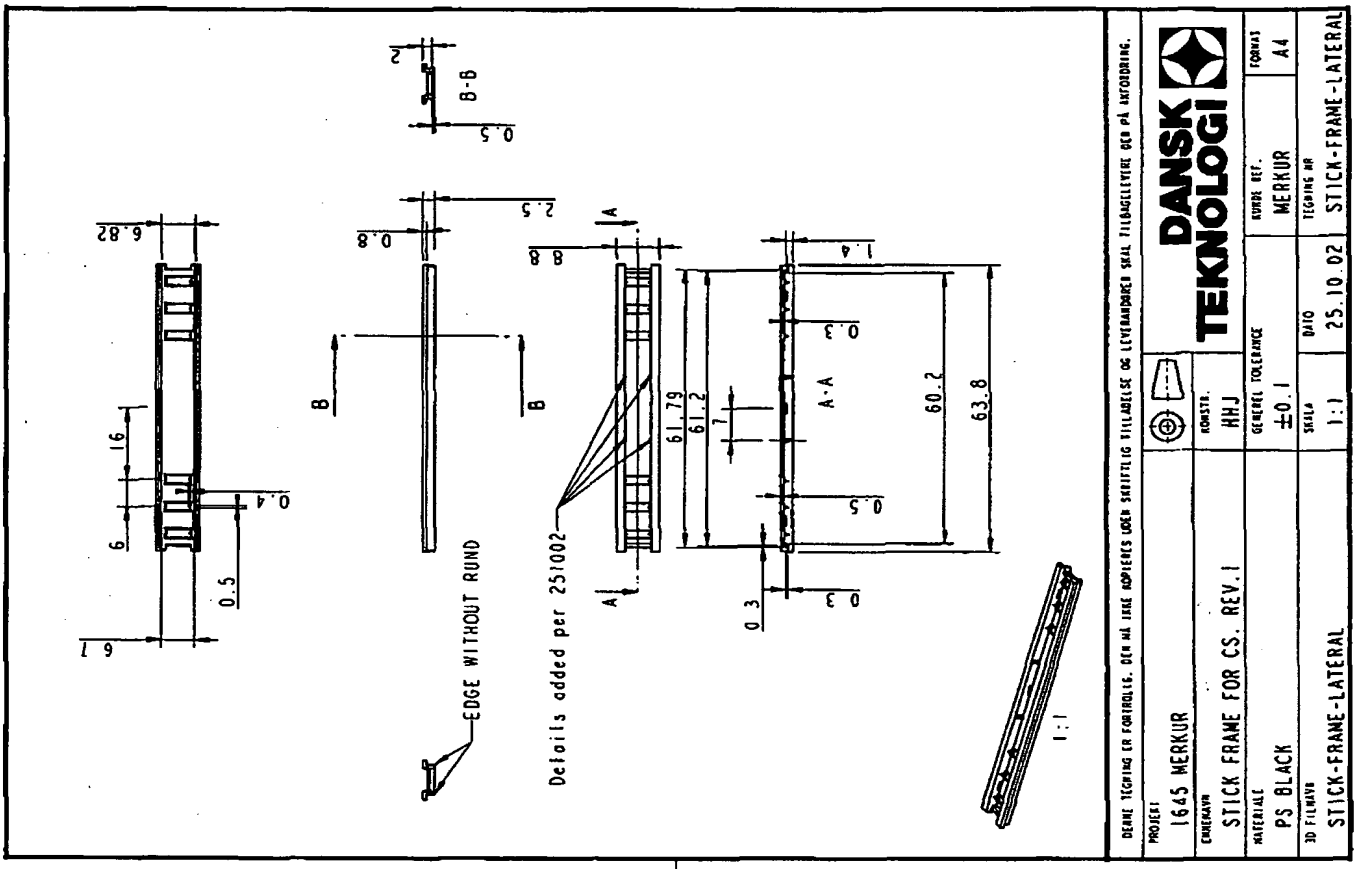


Fig. 49

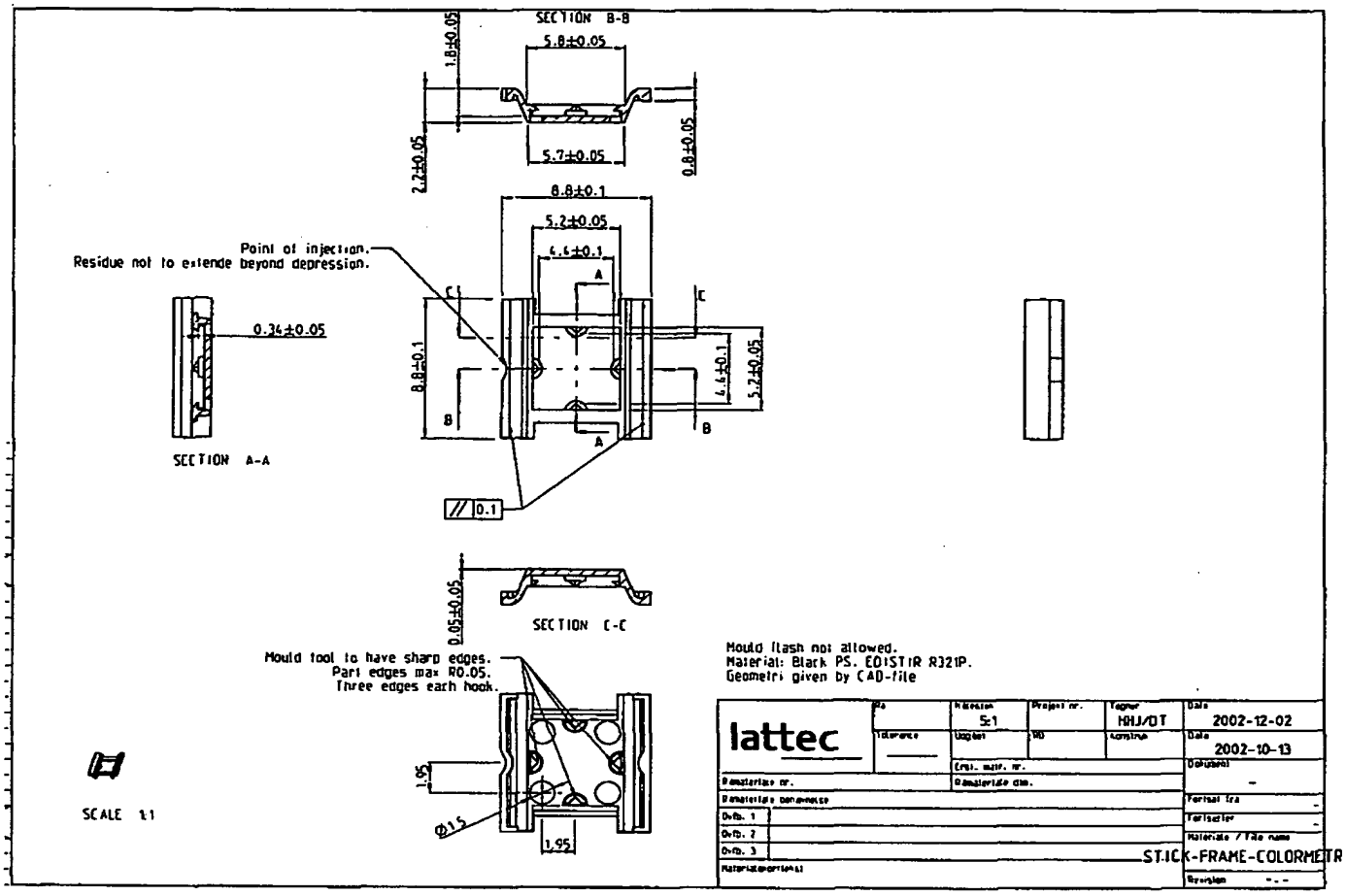


Fig. 50

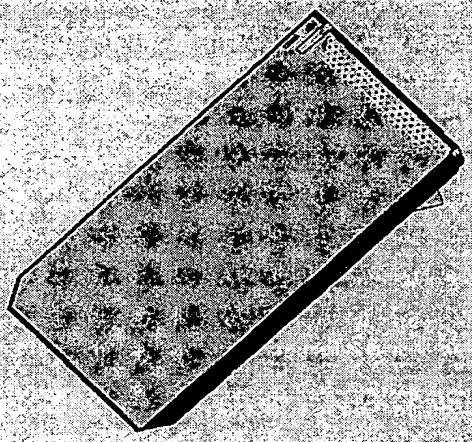


Fig. 51

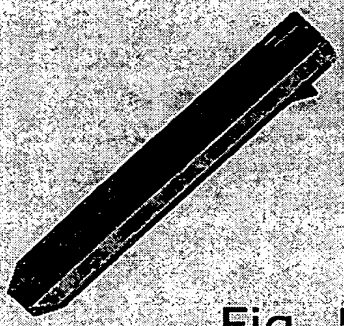


Fig. 52

Fig. 53

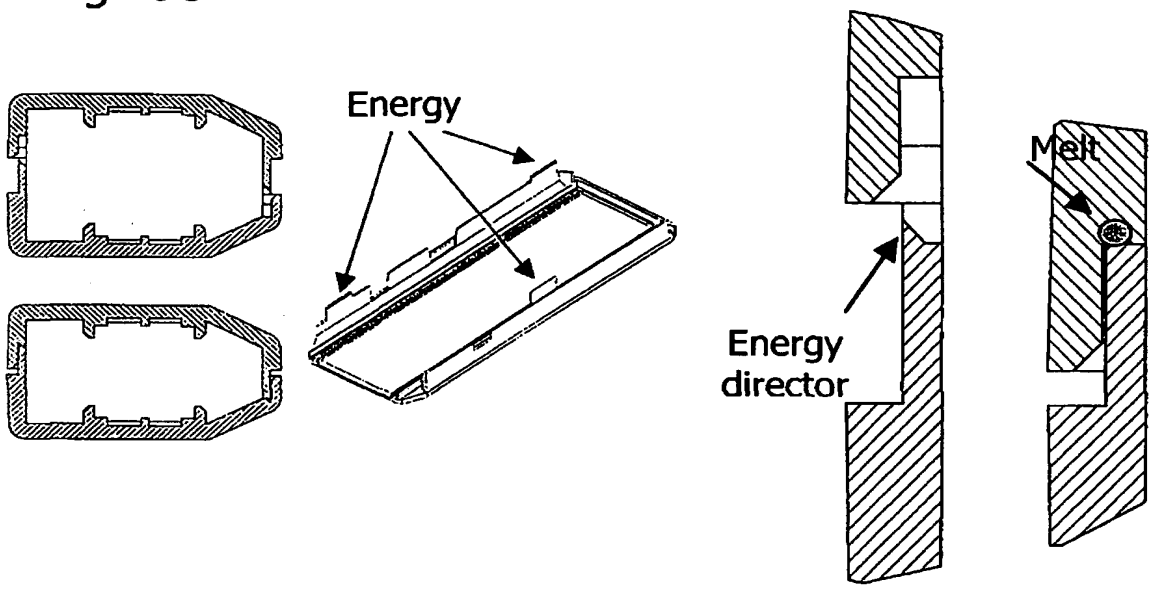
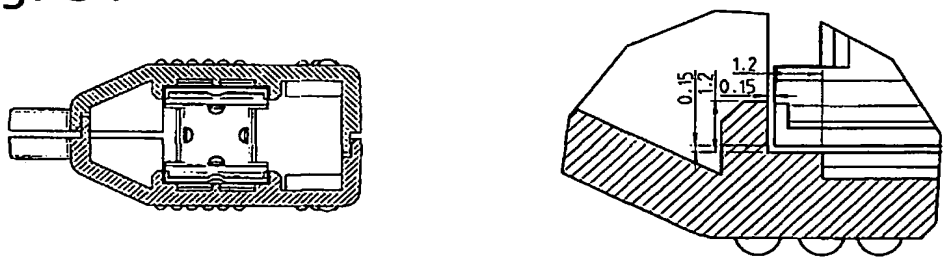
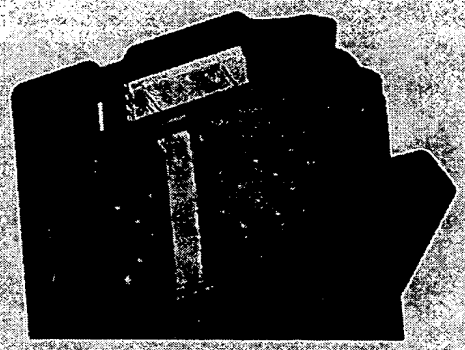


Fig. 54





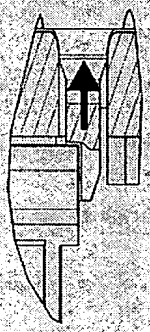


Fig. 55

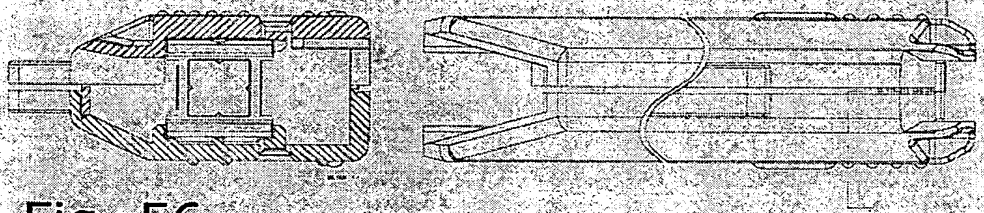


Fig. 56

Fig. 57

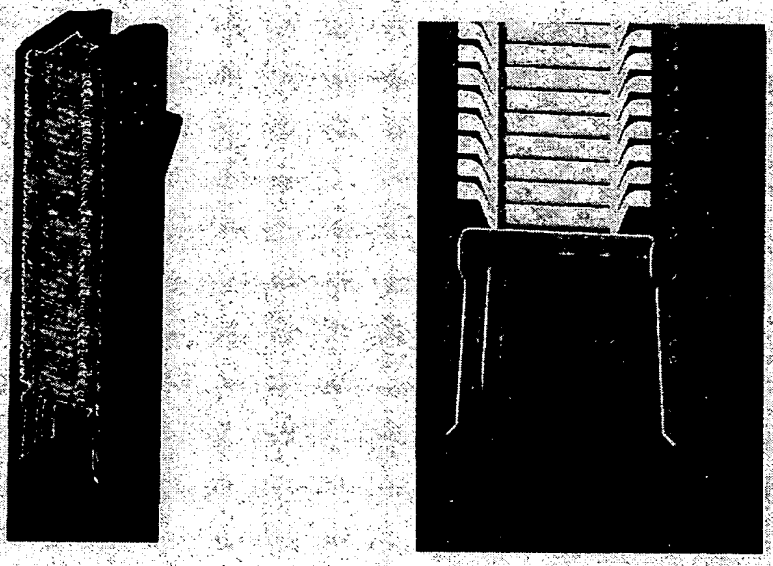


Fig. 58

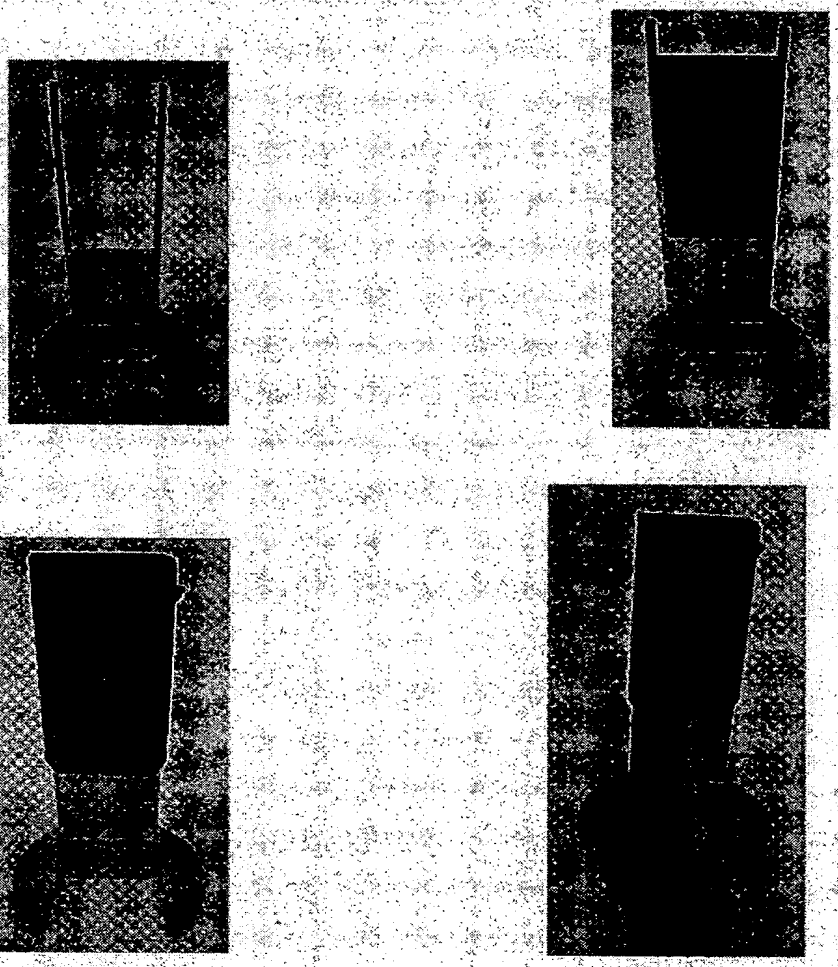


Fig. 59